Assessing Food Safety Risk in Global Supply Chain

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Assessing Food Safety Risk in Global Supply Chain

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Abbreviations

British Retail Consortium (BRC)
Centers for Disease Control and Prevention (CDC)
Control Point (CP)
Codex Alimentarius Commission (CAC)
Critical Control Points (CCPs)
European Food Safety Authority (EFSA)
Euro-Retailer Produce Association (EUREP)
Event Tree Analysis (ETA)
Food and Drug Administration (FDA)
Food and Agriculture Organization (FAO)
Food Supply Chain Risk Management (FSCRM)
Food Safety Management System (FSMS)
Food Supply Chain Management (FSCM)
Good Manufacturing Practices (GMP)
Good Hygiene Practices (GHP)
Gross National Product (GNP)
Good Agriculture Practice (GAP)
Gross Value Added (GVA)
Hazard Analysis Critical Control Point (HACCP)
International Food Standard (IFS)
Interpretive Structural Modelling (ISM)
Key Performance Indicator (KPI)
Performance Measurement (PM)
Performance Measurement System (PMS)
Quality Management Systems (QMS)
Quantitative Risk Assessment (QRA)
Qualitative Risk Assessment (Q)
Risk Assessment (RA)
Supply Chain Management (SCM)
Semi-quantitative Risk Assessment (SQ)
Small and Medium-sized Enterprise (SME)
Supply Chain Performance Measurement (SCPM)
Safe Quality Food (SQF)
The United States Department of Agriculture (USDA)
Total Quality Management (TQM)
World Health Organization (WHO)

1 Introduction

The need for research on food safety risk assessment in global supply chain arises from the increasing interest at national and international level in food safety management systems. The few research studies seeking to draw out the connection between risk and safety management systems and food outbreaks give an indication of defining characteristics of better performing enterprises, but they also reflect the methodological constraints relating to the measurement of health and safety risk along the entire food supply chain. This issue does not appear to have been the focus of academic research and has received limited attention in the popular health and safety literature.

At the center of this research is the intensive study of the health and safety management systems, risk assessments tools and techniques- specifically within food industry domain, food supply chain management and performance measurement in supply chain. Chapter 1 provides a background overview of the food industry, its critical role and issues in terms of economy, social and environmental; following by development of research questions and objectives. Chapter 2 covers intensive review of three main domains of this research that are food supply chain management, food safety management system, and food safety risk assessment. It defines food safety risk assessment as a combination of the management organizational arrangements, including planning and review, the consultative arrangements, and the specific program elements that work together to improve health and safety performance.

In Chapter 3, a novel integrated model is developed and defined in two main phases (1&2) with details. As outlined in Chapter 4 and 5, the case study method is selected for its potential to probe the complex nature of food safety risk assessment model and to explain the detailed processes underlining developed method and test its validity and accuracy. And chapter 6 provides final conclusion to summarize the thesis, its main achievement, and value adding contribution in academic and practical environment.

1.1 Background of the study

Ensuring availability and access to sufficient safe and nutritious food is a key priority that impacts all nations and needs to be ensured today and in the future. At the same time the production and processing of food is a key economic activity providing jobs, skills and training, attracting investments, supporting rural and urban economies and also shaping the future. Based on the economic scale of the food sector, the potential gains from research and innovation, and the structure of the sector with a strong participation of SMEs, the importance of global food security system has become more crucial goal than ever before.

Enabling technologies and scientific applications will be an important element in achieving this goal. Research and innovation actions within this challenge will cover the entire food production chain, from farm to the table including both the supply and demand sides.

The economic and strategic importance of the agri-food sector in Europe is reflected in Eurostat (Eurostat, 2012), accordingly agricultural exports in 2012 were worth €86.2 billion, or 7% of the total value of EU exports; Europe's food and drink industry is among the largest manufacturing industry in the EU with 286000 involved companies that almost half of which are SMEs[1]. In 2012 generated an annual turnover of €1048 billion, with employment for over 4 million jobs.

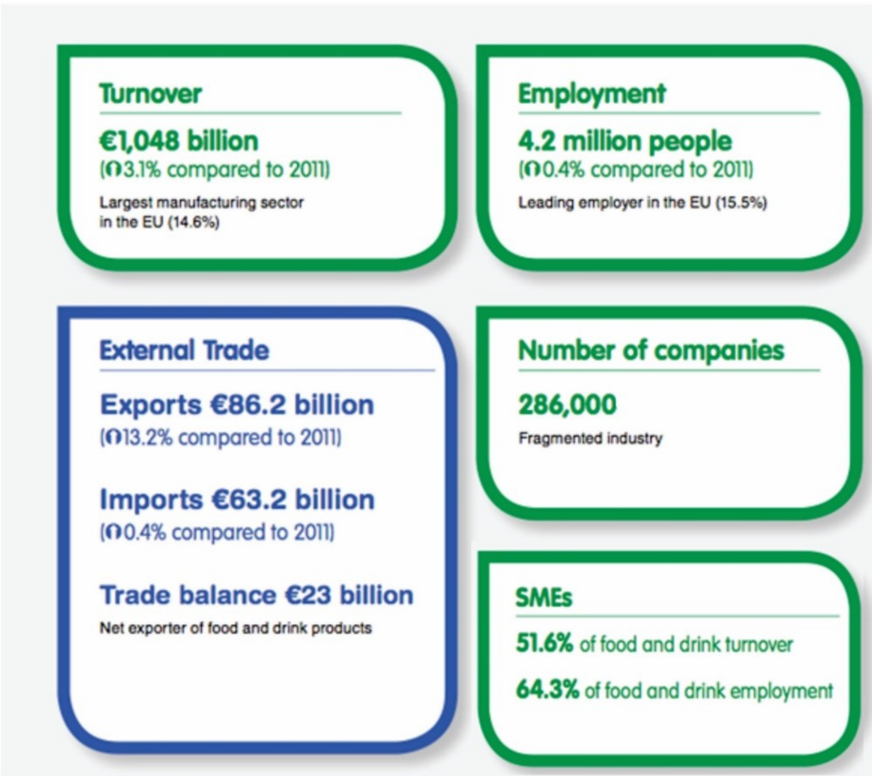

Figure 1:1 Food industry trend in EU (Eurostat, 2012)

Figure 1:2 presents the contribution of the food and drink industry in EU economy, which is about 1.8 % gross value added of total industry in the year 2013, and it shared 14.6 % turnover in the EU manufacturing industry.

Percentage of change in production of manufacturing industry between 2008 to 2013 is compared in Figure 1:3 , as it is shown in this figure, food and drink production has been the second top production

[1] Small and Medium-sized Enterprise (SME): Is defined in Eurostat structural business statistics database as, micro = less than 10; small=10 to 49; medium-sized=50 to 249; large=more than 250 employees.

after pharmaceutical product with the almost constant rate while other products like automotive, machinery, or chemical have had fluctuation and reduction in production volume in this period of time 2008-2013.

These figures show the important role of agriculture industry within European countries from different economical perspectives and consequently critical social and environmental impacts. Among different aspects of agriculture business, food safety and security has always been a vital issue that attracts many attentions academically and practically in order to improve the level of safety in this domain. Actions in this area will support the EU Approach to Food Security; allow for the constant adjustment of food safety policy in view of new scientific evidence (European Consumer Agenda); and provide the integrated EU approach needed for reducing adverse health effect due to poor food safety.

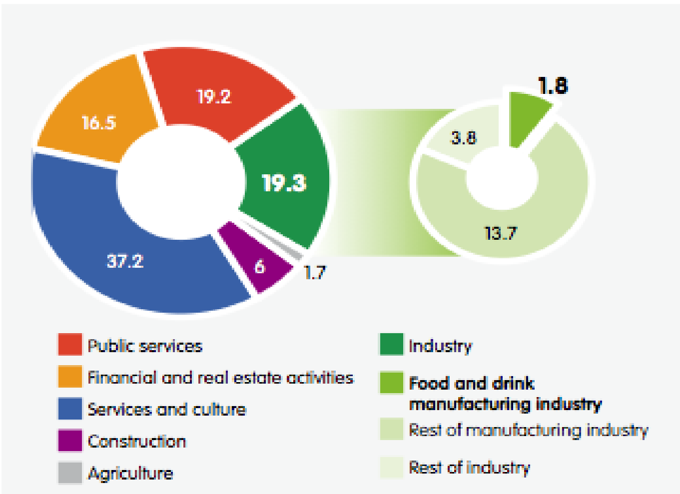

Figure 1:2: Contribution of the EU food and drink industry to the EU economy (% of gross value added[2]) (Eurostat, 2013)

[2] Gross Value Added (GVA) is the value of goods and services produced by a sector minus the costs of the raw materials and other inputs used to produce them.

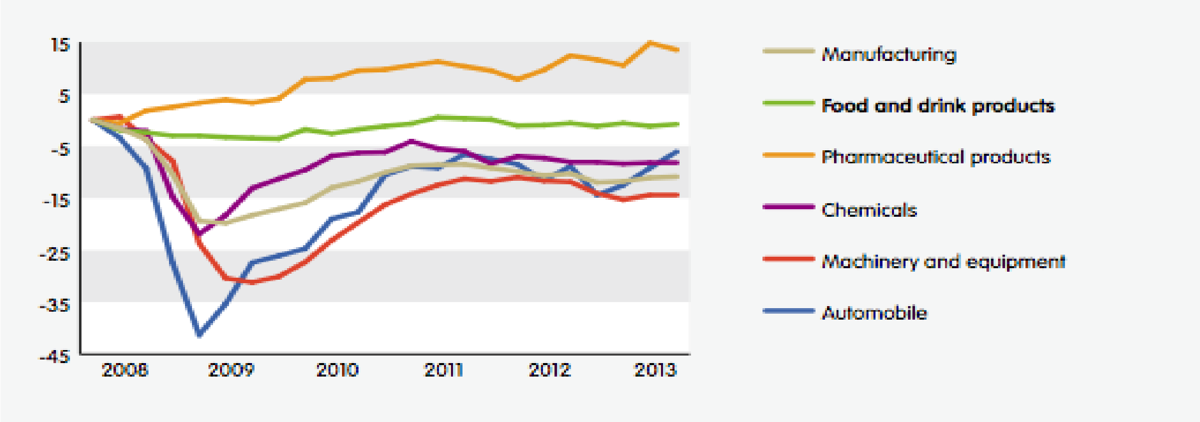

Figure 1:3: Production in the EU manufacturing industry (2008-2013) (Source Eurosstat 2013)

1.2 Food Safety Issues

Nowadays, one of the greatest concerns facing the food industry is the matter of food safety alongside with quality. Food production and consumption is crucial for every society and have many social, economic, and in many cases, environmental effects.

A series of high profile product failures in recent years has reduced public confidence in the ability of producers and governments to assure the safety of food and other products used by consumers (Oliver, 2014). In the past, product recalls were often recognized to local or practical errors in product design, the manufacturing procedure, or inadequate labelling with limited effect. However, today a single product safety problem can have major consequences on a worldwide scale (Marucheck, Greis, Mena, & Cai, 2011). For example existing or emerging infectious diseases and epidemics, spreading faster and appearing more frequently than ever before. Meanwhile, modern demographic, environmental, technological and societal conditions favour the spread of these diseases, at a global scale. As for the food sector, foodborne outbreaks can unsettle consumers' trust and have negative effects on trade and the economy of the sector. They also pose a threat to the sustainability of the food chain and undermine food security. This raises new challenges beyond national borders to, public health and food safety scientists and experts, policymakers, and populations.

The pioneer law concerning the quality of food products, known to be "German Beer Purity Law" dates in 1516 (Dornbusch, 1997). Nowadays, there are numbers of regulations, laws, standards, and techniques regarding the food safety and quality. However, food failure outbreaks still occur in global context. Table 1:1 presents some examples of food safety incidents, as it is presented in this table the source of incidents, country of failure outbreaks and the severity of outcomes are very vast and in international context.

With respect to the safety, food supply chain is very vulnerable due to the following main reasons: first, the characteristics of products that are natural and mostly perishable and have the potential hazards if not managed in safe and timely manner (Akkerman, Farahani, & Grunow, 2010). Secondly, food supply chains have expanded due to globalization and tend to be in longer distance that leads to higher risk exposure (Henson & Reardon, 2005; Speier, Whipple, Closs, & Voss, 2011). Third, global food supply chain are at risk of intentional or unintentional adulteration and could be also at risk of terrorist threats (Y. Liu & Wein, 2008; Speier et al., 2011). It is claimed by (Harl, 2002), among seven main areas of terrorism vulnerability in the US, five are connected to the food supply chain. Therefore, the proper management of the food across supply network is necessary to ensure the final products are safe for consumers.

Voss et al (2009) in their research investigate the trade-offs among safety, price, quality and delivery in supplier selection process in the food supply chain in U.S. and they found out generally safety tend to be in lowest concern comparing to three other criteria (quality, delivery, price). They assume that this low priority could be the driving factor behind the food safety outbreaks.

Food safety failures not only have impact on consumer but also on involved companies and in worst scenario when the incidents leading to deaths or illness (Trienekens & Zuurbier, 2008). According to Mead et al. (1999) in the U.S. alone, estimation of foodborne pathogens account for 76 million illnesses and 5000 deaths, among all human errors and food safety procedures limitations are some of the reasons behind food safety risks for end consumers. (Thomsen & McKenzie, 2001)

High profile outbreaks such as adulteration of powdered milk with melamine in China in 2008 (Spencer, Greenbaum, Ginsberg, & Murphy, 2009) or the Salmonella outbreak caused by peanut butter paste in America in 2008 (Layton & Miroff, 2011) had major severity and scales with serious consequences for involved people. The Peanut Corporation of America has been closed down after one year in February 2009 (Layton & Miroff, 2011). Sanlu, the company responsible in China, faced bankruptcy and a number of company officials have been sentenced to jail and death (Spencer et al., 2009).

Table 1:1: selected high profile food safety incidents (Colchester & Colchester, 2005; G. EFSA, 2008; Layton & Miroff, 2011; Roth - Walter et al., 2008; Sheeran, 1992)

Year	Incident	Description	Company
2011	E.coli contamination of bean sprouts	As of this printing, an outbreak of a rare form of E. coli killed 37 people and sickened more then 3000 in Europe. European Union approved 210 million euros ($286,78 million) in emergency aid for vegetable Farmers affected by the crisis.	Sprout farm in northern Germany near Hamburg
2008-2009	Salmonella outbreak ill peanut butter	Contaminated peanut butter paste is linked to nine deaths and 637 cases of Salmonellosis in the U.S. and	Peanut Corporation of America

Year	Incident	Description	Company
	paste	Canada with thousands more illnesses suspected. The incident triggered that largest product recall in U.S. history affecting near 4000 products	
2008	Dioxin in Irish pork dioxin	Large international recall of Irish pork products due to contamination with dioxin. Pork supplies to a total of 2.3 countries was affected, 13 within the European Union	Millstream Power Recycling Limited
2008	Melamine in Chinese milk products, including milk powder	contamination of milk and infant formula, as well as other milk-based products due to adulteration with melamine. An estimated 300,000 illnesses were reported and six infants died	Chinese milk producers Sanlu Mengniu, yili, and Yashili
1986-1987	Mad cow disease	Epidemic of bovine spongiform Encephalopathy (BSE) or "mad cow" disease in U.K. was suspected to be the cause of variant Creutzfeldt-Jakob Disease which affected hundreds of people	Multiple producers in U.K.
1858	Arsenic poisoning in sweets	An accidental contamination of sweets with arsenic poisoned more than 200 people and resulted in about 20 deaths, This incident led to the passage of the Pharmacy Act 1868 in the UK and legislation regulating the adulteration of foodstuffs	Bradford, England

1.2.1 Social aspect

The importance of food safety as a public health issue continuously increases. Outbreak of foodborne diseases damages public trust and causes loss in economy, as well as unemployment and social impacts (CAC, 2011). From a global point of view, foodborne diseases are expanding and international food industry is challenged by continuous conflicts over food safety and quality requirements (FAO, 2012). Many critical and life-long diseases, from diarrhoeal diseases to various forms of cancer have erupted to unsafe food. According to the World Health Organization (WHO, 2007) waterborne and foodborne diarrhoeal diseases together, put around 2.2 million people to death annually, out of which 1.9 million are children. According to the reports, the percentage of people who are suffering these illnesses reaches up to 30% annually, in the industrialized countries. For example, in the United States, according to the estimates, 76 million cases of foodborne diseases occur each year, out of which, 325000 result in hospitalization and 5000 end dead. The underlying food safety problems can be better manifested regarding the high prevalence of diarrhoeal diseases in developing countries. (WHO, 2007)

1.2.2 Economical aspect

According to (WHO, 2002), foodborne diseases not only influence the health condition of people, but also they have economic effects on people, societies, trades and countries. These illnesses highly affect economy, and reduce the economic productivity. Besides, they impose crucial burden on health-care systems. There are not much information on economic effects of food poisoning and foodborne diseases, however, according to a report in 1995, in the US, seven pathogens caused 3.3- 12 million cases of foodborne illnesses, which cost approximately 6.5- 35 billion annually. Lately, Robert L. Scharf, a former Food and Drug Administration (FDA) economist, estimated the total costs caused by foodborne diseases to be a combined $152 billion annually, across the nation (Scharf, Levkoe, & Saul, 2010).

The United States Department of Agriculture (USDA) estimates that five major types of foodborne illnesses that cause medical costs and reduction in productivity, cost up to $6.9 billion annually (Vogt, 2005). In the European Union the annual costs imposed on health care system by infections caused by salmonella are evaluated to be about 3 billion euros (Kok Seng, 2009). Just five foodborne diseases outbursts in England and Wales in 1996 cost an estimated UK£ 300–700 million in terms of medical costs and values of lost lives. In Australia also, the estimated 11,500 daily cases of food poisoning cost up to at AU$ 2.6 billion annually. Multiple factors can increase the incidences of foodborne illnesses due to foodborne hazards, which is the result of fast rate change in the world (Kok Seng, 2009).

1.2.3 Environmental aspect

Concerns about environmental consequences of food supply chain are growing with the development of international food trade. Comparing to the past, food is travelling far more distance from the farm that is produced to the kitchen that it is consumed. As a result, energy consumption increase, more resources are needed, and emission of Green House Gases rises in food chain, including production, consumption, and transportation. Carbon labelling use (i.e. carbon footprints of the products) initiation and the concept of food miles (the distance food travels from producer to consumer) is indicative of food chain needs for solutions which are more environmentally friendly, in order to reduce the environmental effects such as global warming and pollution.

In numerous countries, one of the issues concerning food safety and quality is food deterioration. Food decline is inefficient, uneconomical, and unreasonable; it can influence businesses and buyer confidence. Commonly, all foods have a restricted life time and most foods are perishable. Perishable foods require refrigerator and temperature control along the chain (Aung & Chang, 2014). The International Institute of Refrigeration (IIR) shows that around 300 million tons of produced food is wasted yearly through insufficient refrigeration and foodborne illnesses around the world. In the United States, the food business yearly expenses USD 35 billion value of ruined merchandise and are a major issue for the earth (Estrada-Flores & Tanner, 2008).

In UK 6.7 million tons of nourishment are waste annually. The Waste Resources and Action Program (WRAP) evaluates that 33% of the nourishment purchased is unusable due to unsafe condition (Lipinski et al., 2013). Each ton of nourishment waste is in charge of 4.5 tons of carbon dioxide. The sustenance waste which are tossed make methane, an intense greenhouse gas which is more than 20 times stronger than carbon dioxide and have a noteworthy ecological effect (Ventour, 2008).

1.3 Research Questions and Objectives

The subject of product safety and security is almost a new topic in supply chain risk management domain, and during the recent years it has received increasing attention in academic and literature (Marucheck et al., 2011; Pyke & Tang, 2010). For example Narasimhan and Talluri (2009) investigated how food safety risk could be manifested along the supply chain, using a food safety accident. Although the literature focusing on risk management within a supply chain continues to grow, there is no global accepted categorization of the various kinds of risks experienced within supply chain. Finch (2004), T. Y. S. Lee (2008) and Sodhi and Tang (2012), among others, offer different classifications and categories. However, most of these risk typologies address events that may have negative consequences with respect to the flow of product through the supply chain, and they do not address the impacts of undesired events on safety of the products.

Supply chain of the food product or Food Supply Chain Management (FSCM) due to its nature of products (i.e. perishable products) and its complex structure has more demand on safety risk management. However, there is lack of knowledge in concern with the risk of a product safety, its composition, prosperity of its packaging and labelling, logistics and storage, in FSCM when the consequence of some deviation can result in the health of consumers.

The review of the current pattern in the food safety and quality chain by Gebresenbet and Bosona (2012) reveals three main trends in the FSCM:

A. Globalization of the food supply chain, increasing the supply chain risks, and increasing the demand for regulations and control along the entire food networks.

B. The development of incorporated supply chain and connecting producers and different partners;

C. Growth of customers' interest for food safety, quality, nutritious product and animal welfare.

Nonetheless, to date, the linkage among different parties in the food safety supply chain has a slower rate compare to the other industries. This connection demands for more collaboration and joint venture of the firms within the food supply chain safety risk assessment, in order to improve the food safety. Quality and safety of raw materials, production, packaging, logistics, warehousing and retailers are essential in food safety and quality.

As mentioned above, while there have been many attempts in academia and practical environment to improve the food safety in general (McMeekin et al., 2006; Mensah & Julien, 2011; Ying, Yanyan, & Xiaoyan, 2014), there is a gap of knowledge and empirical techniques to apply food safety risk assessment along the entire food supply chain; and as it is presented by Marucheck et al. (2011) in the global supply chain product safety and security, research will be needed to identify if the entire food process leads to safer products and fewer recalls. Majority of the existing techniques and models either are limited only in one node of the food networks (e.g. production, or storage), or the models are very general without specific tools that cause difficulty in implementation and application by practitioner.

Therefore, this research aims to bridge this gap in academic and practice by answering the following main research questions:

- *What are the current issues in the food supply chain safety management?*
- *What is the role of risk assessment within the food safety management?*
- *How risk assessments techniques can be applied in the entire food supply chain?*

Hence, food supply chain is the domain in this work which suffers a lot of uncertainty in its functioning. This research discusses the various research works in the area of food supply chain, food safety management, and risk assessment tools and techniques. The main objective of the proposed work is to create a model which analyses the various risks involved in a food supply chain. (Chapter 3)

The developed model is validated with the help of case studies on food products manufacturing firms in Italy. The various types of safety risks involved in the food industries were selected based on the literature study and in consultation with the experts in food industry. (Chapter 4&5)

The scope of this research is a sequenced-based method on identification and characterisation of food born hazards using Risk Assessment (RA) techniques in combination of Key Performance Indicators (KPI) along the entire food supply chain. It will facilitate the hazards monitoring, including rapid identification and comparison, and position mapping in the food chain. It includes predictive models to identify ‘high-risk’ areas by analysis of the drivers of consequences, and their impact. It will ensure links and consistency with existing networks and standards of food industry to harmonised data collection,

management and sharing and better management tools for authorities, and businesses. This research collaborates in an interdisciplinary approach on a global scale by development of tools and methodologies for food risk assessment between authorities and firms.
The expected impact of this study is faster identification of hazards and better and more integrated surveillance tools for improving the food safety, covering the entire food supply chain by using more integrated method. It could improve standardised processes at European and International level by using more harmonised and economical approach. Improving the food safety will improve the public health, minimize market losses and facilitate international trade, thus increasing the competitiveness of the food and agricultural sector. Overall, the sustainability of the food chain will be reinforced and food security will be enhanced.

2 Review of Literature

The following chapter provides a framework for the research and sets the scope for the academicals study. Firstly, the concepts of supply chain management and food supply chain are defined to set the baseline for the study. Next section covers food safety management systems, why and how the supply chain actors need standardisation and why they need to cooperate to create the best possible food safety system. Next, risk management concept is described and different tools and technics in risk assessments are discussed.

2.1 Supply chain Management (SCM)

Supply chain management (SCM) perception has been developed during the time. The term SCM was introduced in the early 1980'; and one of the known definitions that is presented by the Global Supply Chain Forum in 1994 and modified in 1998 (Lambert, Cooper, & Pagh, 1998), is as follow: "Supply chain management is the integration of key business processes from end user through original suppliers that provides products, services and information that add value for customers and other stakeholders."

Bagchi, Chun Ha, Skjoett-Larsen, and Boege Soerensen (2005) presented another definition of supply chain management.

"Supply chain management consists of the entire set of processes, procedures, supporting institutions, and business practices that link buyers and sellers in a market place".

Mentzer et al. (2001) defines supply chain as "a set of three or more entities (organizations or individuals) directly involved in the upstream and downstream flows of products, services, finances, and/or information from a source to a customer". There are many diverse definitions of supply chain in the literature, however, the essence is the same and they are all similar. The levels of supply chain complexity are presented by Mentzer et al. (2001) as "direct supply chain", "extended supply chain" and "ultimate supply chain". A direct supply chain Figure 2:1, consists of downstream flows, supplier, organization and customer.

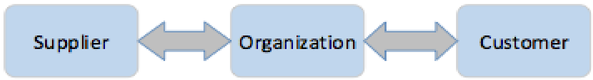

Figure 2:1 Direct supply chain

The extended supply chain Figure 2:2, includes suppliers, intermediate supplier, organization, intermediate customer, and customers.

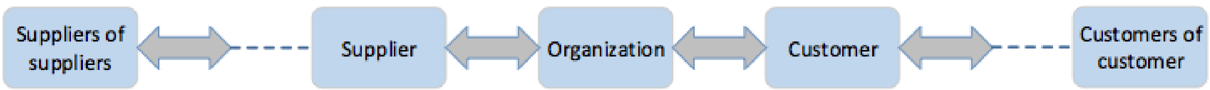

Figure 2:2 Extended supply chain

The ultimate supply chain involves all parties or individuals from the ultimate supplier to the ultimate customer in Figure 2:3. It could consist different levels of suppliers, intermediates, financial providers, logistics providers, distribution, marketing and sales, and customers.

The type of supply chain and its extent could vary depending on the structure of the organization, industry and kind of its business operation.

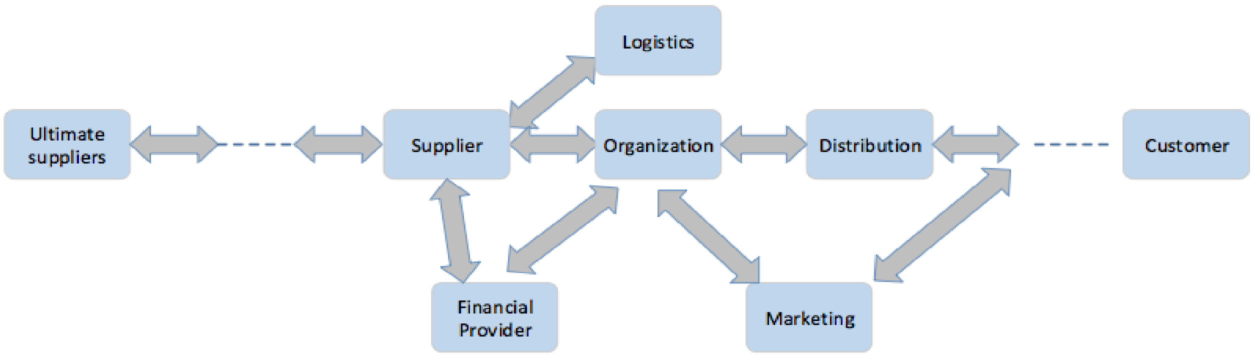

Figure 2:3Ultimate supply chain

The main characteristics of supply chain management according to Bagchi et al. (2005) are as follow:

1. SCM has a systematic approach and views the supply chain as one entity rather than several different parts. The objective is to manage the flow of product optimally from the supplier to the customer.

2. Strategically use and synchronize resources and capabilities in collaboration.

3. Increase customer value by having all actors throughout the chain focusing on the end customer.

Information sharing, sharing of risks and rewards, cooperating, integrating behaviours and processes and maintaining long-term relationships, are the main important factors in SCM. Collaboration is often referred to as the driving force behind effective supply chains (Horvath, 2001), Collaboration in supply chains is defined as ”two or more companies sharing the responsibility of exchanging common planning, management, execution and performance measurement information” (Min et al., 2005).

Performance Measurement System (PMS) is another important concept in the SCM practice. In the literature PMS in supply chain or supply chain metrics, increase the success to reach the supply chain objectives and collaboration (Chae, 2009). Because, metrics facilitates align processes in the supply chain and empower cooperative behaviour across partners. The metrics can also move managers' attention from firm performance to total supply chain performance. Using joint performance measurements, the supply chain partners can apply a common strategy that attains the set objectives (Chae, 2009).

2.2 Food Supply Chain Management (FSCM)

Food supply chain is described with its unpredictability, which is a standout amongst the most essential reasons behind what makes the food safety complicated. There are a lot of connections in food network, interconnected with one another, and if one of them is out of work, the issues of food safety will be transfer, even putting dangers to human health. In this way, food supply chain safety is discriminating to ensure safe and efficient food supply.

2.2.1 Background of FSCM

The definition of SCM (Supply Chain Management) has evolved and broadened the scope of SCM, while these definitions are still focused more on manufactured products and services, and less attention to agriculture. However, agriculture business plays a major part in the world economy and involves many sections and professions within business economy.

The SCM of agri-fresh product or Food Supply Chain Management (FSCM), has more complex structure as compare to other SCMs. This is due to its perishable nature of products, high demand and price fluctuations, long distance between point of origin and consumption, and growth in customers' concerns for food safety. (Van der Vorst & Beulens, 2002).

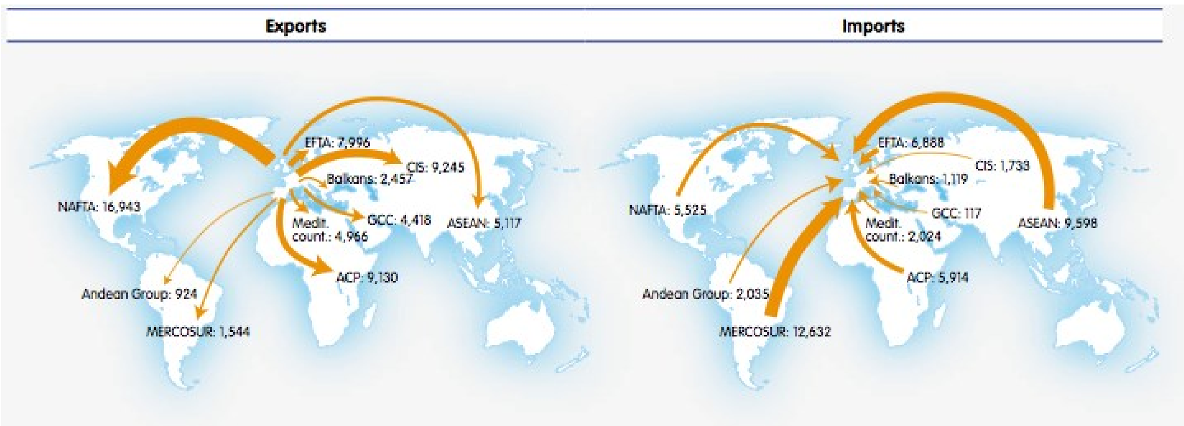

Figure 2:4: EU trade by region, 2012 (€ million).(Eurostat, 2012)

The network of raw material producers, food processors, warehouses and retailors are growing in a fast rate. On the other hand, the food division assumes a huge part in economy being one of the principle donors to the Gross National Product (GNP[3]) of numerous countries, especially in developing countries. As indicated by the European Commission (Eurostat, 2012) the food and beverage industry is one of Europe's most critical segments comprising of more than 286 thousands organizations that give employments up to more than 4.2 million individuals. Table 2:1, shows the main trading partners for European food and drink products in 2012, and the value of their trade in Million Euro. As it is clear in this table US has been the first exporter and Brazil the first importer to the Europe. Furthermore, the EU agricultural products trade have increased to a great extent from 2002 to 2012, and the exports have almost doubled from about 43 to 86 Billion Euro Figure 2:5.

Table 2:1:Top EU trading partners 2011-2012 (€ million)(Eurostat, 2013)

Exports			Imports		
	2012	12/11 %		2012	12/11 %
USA	13,580	13%	Brazil	7,358	5%
Russia	7,959	10%	Argentina	4,757	-12%
Switzerland	4,900	5%	USA	4,318	6%
China	4,595	30%	Switzerland	3,904	10%
Japan	4,265	15%	China	3,845	-5%
Norway	2,886	6%	Indonesia	3,196	2%
Hong Kong	2,732	-2%	Thailand	2,643	-7%
Canada	2,571	13%	Turkey	2,273	7%
Australia	2,039	18%	Malaysia	2,114	38%
Saudi Arabia	1,953	16%	Norway	2,029	3%

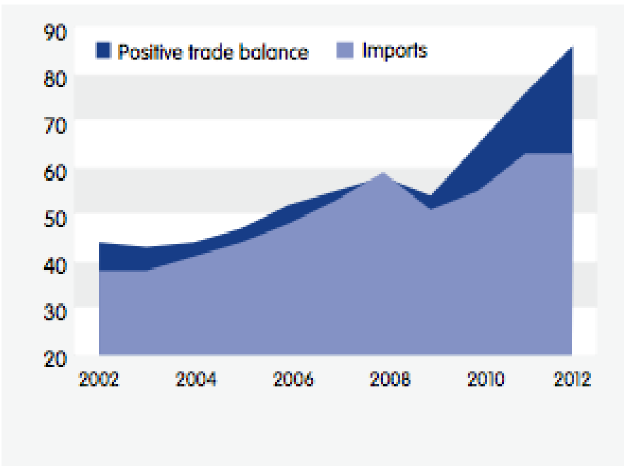

Figure 2:5: Food and drink trade balance, 2002-2012 (Billion Euro) (Source Eurostat 2013)

3 GNP is a measure of a country's economic performance, or what its citizens produced (i.e. goods and services) and whether they produced these items within its borders. (BusinessDictionary.com)

2.2.2 FSCM Issues

The globalization of food market and production has led to greater distance between producers and consumers that cause more risk for foodborne illness and public health. Therefore, there must be a nonstop attention for the safety and quality of the products, from the time the raw materials enter the production to the time the product achieves the consumers. (Gorris, 2005)

Perishable foods, such as fish, meat, milk, and more, can undergo safety impairment rapidly along the supply chain, even after they leave production step before coming to the purchaser. Thus, keeping food safe and in great quality is a complex task, specifically when it travels through the different nodes along the supply network, and it demands for real time tracking and tracing. Besides, it results in more demand for collaboration in supply, production, transportation, storage and distribution of food products, as any single source of failure in food safety can cause worldwide outbreaks.

In consequence of this requirement in the food supply chain, food safety has observed more attentions, for public, policy makers, companies, researchers in an international level. Following this changes, a significant increase in public and private standards has emerged which has affected on food production, distribution and business (Fulponi, 2006). Nevertheless, food safety standards represent significant differences around the world. These standards are in both public level (i.e. Codex Alignments, regional countries, and individual nations) and private level (firms and supply chain demands and customers requirement), which both have different level of protections. (Henson, 2008)

For example ISO 22000 is a quality management framework aiming to food safety issues in food production and can be connected to a wide range of association in the food supply chain. As it is mentioned by Aggelogiannopoulos, Drosinos, and Athanasopoulos (2007), ISO 22000:2005, Food safety management outlines:

"...aims to guarantee that there are no fail connections in the food supply chain." Food safety and quality are best guaranteed by an incorporated, multidisciplinary methodology, considering the entire food chain.

2.2.3 Food Supply Chain Risk Management (FSCRM)

Risk management in supply chain have been discussed from various perspectives in the literature (Jüttner, Peck, & Christopher, 2003). Namely risk of supply (De Boer, Labro, & Morlacchi, 2001), demand (Porteus, 2002), information flow (H. Lee, Padmanabhan, & Whang, 2004), materials flow and the safety and quality performance (Christopher & Lee, 2004). Because these factors are linked to different functional areas within companies, the risks can be interpreted in several ways and it spans over organisational borders (Svensson, 2001). As it is argued by Gaudenzi (2009) risk management in entire supply chain, reduce overlapping all processes and able to mitigate the negative effects of risks and enhance success and profit at the same time. Hence risk management should be connected with supply chain performance concerning the specified goals of the processes and supply chain networks.

The current food supply chain studies mainly has a qualitative view of risk analysis factors, and develops some countermeasures to prevent or solve the risk. For example, Chen and Feng (2007) argued that food supply chain is different from other industry concerning the risk, because in food industry risk mainly consists of technological risk, information risk, quality and safety risk. They presented five key points in order to strengthen the management of food safety: accelerate the procedure of agricultural standardization; application the entire process supervision of inputs, develop a product traceability system, and establish agricultural production operator self-discipline mechanism, create a comprehensive system of agricultural product quality and safety risk assessment.

Christopher and Peck (2004) argued the challenge to food business today is to manage and mitigate the risk through creating more resilient supply chains. Likar and Jevšnik (2006) studied the process of cold chain logistics, and how to find out key hazard point in the cold chain with the adoption of Hazard Analysis Critical Control Point (HACCP) methodology. The study concludes using cold chain temperature monitoring technology leads to food safety improvement. Tang (2006) investigated the food supply chain risk from different perspectives of food quality and safety, logistics, and information sharing risk. He presented a method for food supply chain risk assessment, and proposed the corresponding risk prevention measures.

Liu and Wang (2011) analysed the current problems and situation of the food supply chain and suggested following points to solve food quality safety issues: improving the entire supply chain, scale of operation, national supervision, and set up professional logistics companies and logistics system. Diabat, Govindan, and Panicker (2012) developed a model which analyses the various risks involved in a food supply chain with the help of Interpretive Structural Modelling (ISM). The types of risks are clustered into five categories and risk mitigation is discussed. Leat and Revoredo-Giha (2013) tested one of Scotland's major pork supply chains to identify the key risks and challenges involved in developing a resilient agri-food supply system, and found out supply chain vulnerability to risks reduce through horizontal collaboration amongst producers, and vertical collaboration with the processor and retailer.

In order to explore broadly the literature in the food supply chain risk assessment and understating the current situation in this academic domain, we perform a Scientometrics Analysis in the next section. (2.2.4)

2.2.4 Scientometrics Analysis Study of Food Supply Chain Risk Assessment

Scientometrics is the quantitative study of the disciplines of science based on published literature and communications. It intends to identify the emerging areas of scientific research, examine the development of research over time, and explore the geographic and organizational distribution of research. The study was conducted on 266 articles on food supply chain risk assessment published between 1996 and 2014. Web of Science, the citation database of Thomson Reuters, was used to find the articles and extract the research findings. As Scopus and the citation databases of the Web of Science are the two most important tools for scientometrics studies (Miguel, Chinchilla - Rodriguez, & de Moya - Anegón, 2011).

In order to find the articles, we first sought for equivalent terms for food safety in thesaurus, such as UNESCO and ERIC (ERIC: Thesaurus, 2014, UNESCO thesaurus, 2014). Then we write a search formula (food AND (risk OR hazards) AND (safety OR shelf life) AND (supply chain OR supply network) for advance search, to find out the whole articles of this subject area. Afterwards, we separated the documents based on the title, abstract, and keywords. After that, the results were limited from 1996 to 2014 publications. Then, the contents of the documents were scanned to ensure their relevance. After excluding the unrelated documents or records with poor relevance, the researchers were left with 266 documents to analyze. The first phase of the analysis included publication date, document types, language, authors and their affiliations, and the countries where the articles were developed. Then, the subject areas of the documents (in total) were analyzed according to their publication dates.

2.2.4.1 Results of the study

According to the results, the first article to be found on food supply chain risk assessment belonged to 1996. There were few documents (36 records, %13.53) on food supply chain risk assessment from 1996 to 2004. The results from 1996 to 2014 (266 documents) have been presented in Figure 2:6. According to this figure, with a negligible number of ups and downs, the number of publications on food safety increased steadily from 1996 to 2014, with the greatest number occurring in 2013.

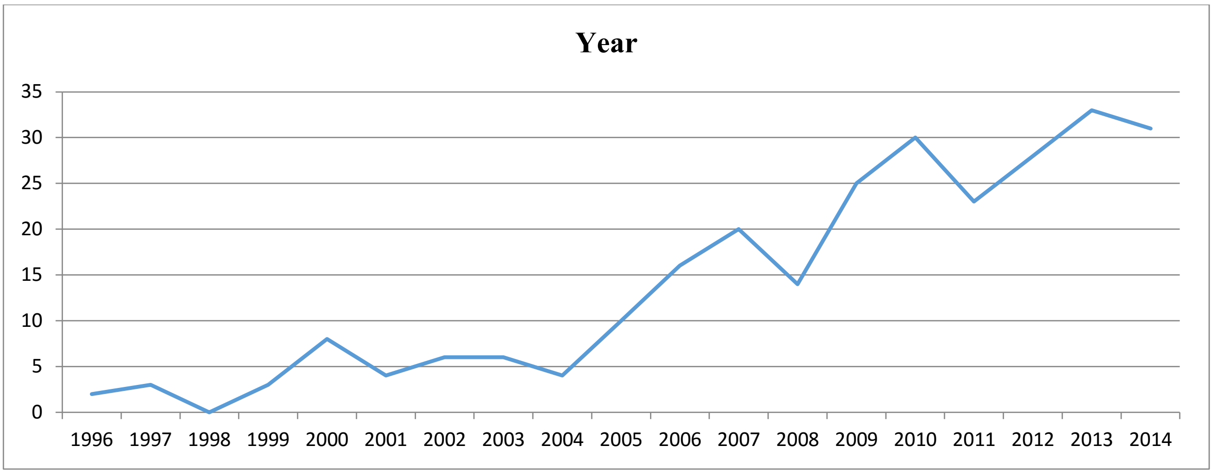

Figure 2:6: Distribution rate of food supply chain risk assessment publications based on the date of publication

Data analysis based on document types indicated that out of the 266 documents under study, 199 (64%) were articles and 82 (26%) were proceeding paper. The remaining 31 items (10%) belonged to other types of documents. Figure 2:7

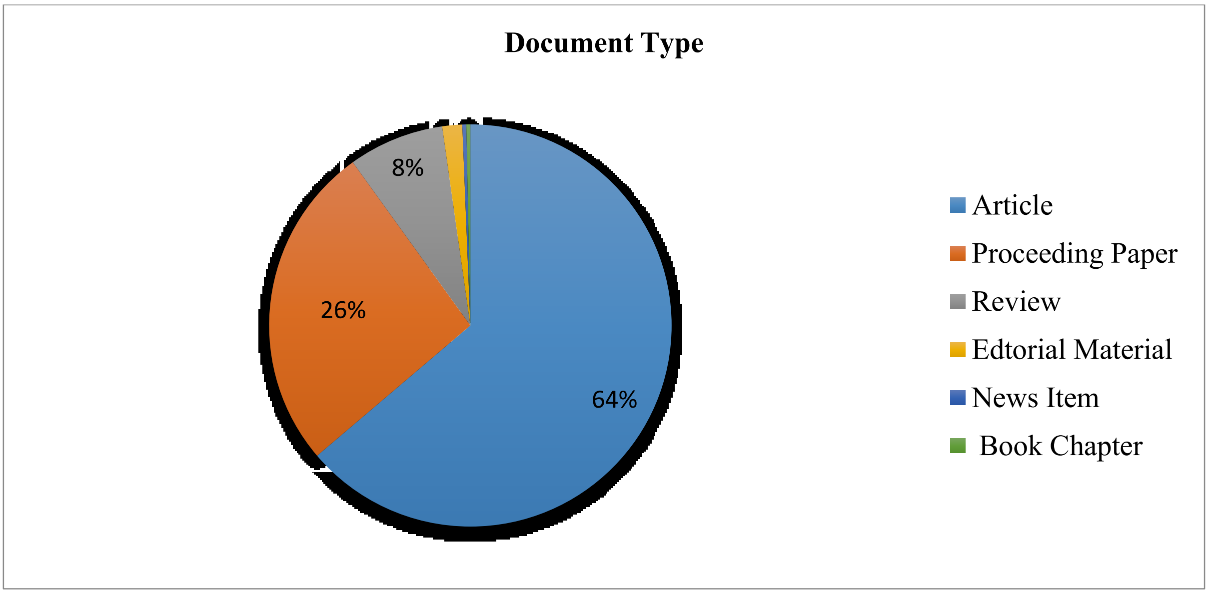

Figure 2:7: Distribution rate of food supply chain risk assessment publications based on document types

Considering the language of documents, 260 documents (97.74%) were published in English, 2 in German and 4 articles in other languages.

Distribution of the countries publishing the documents has been presented in

Figure 2:8. Accordingly, the United States with 64 documents (24%), the England with 50 documents (18.80%), and Netherlands with 42 documents (15.79%) had the greatest contribution to publishing the documents.

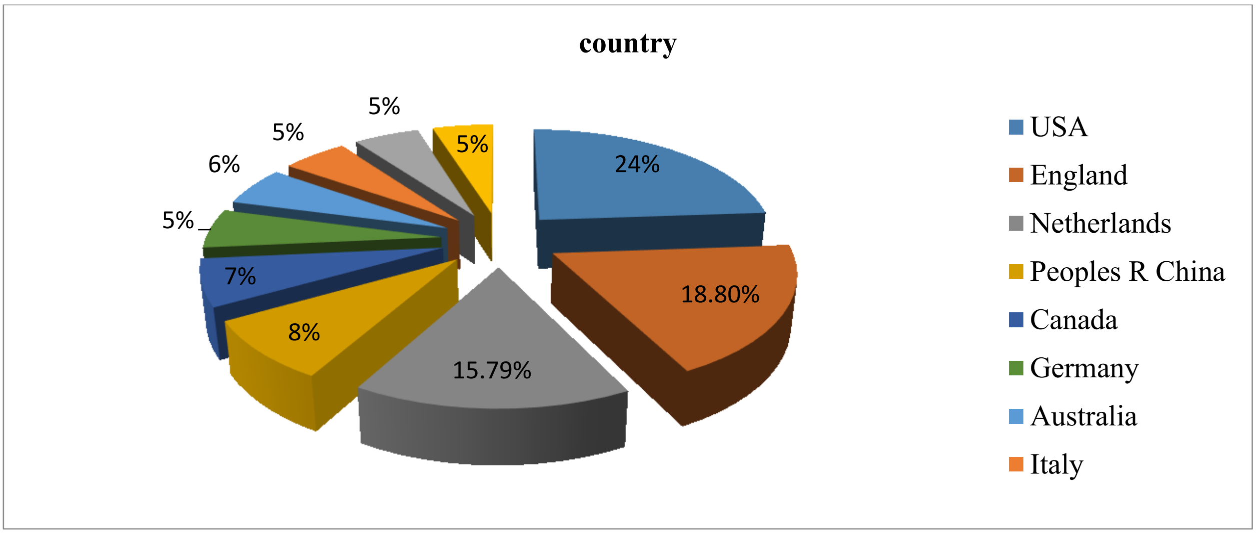

Figure 2:8: Distribution rate of food supply chain risk assessment publications based on their affiliated countries

According to the results, the most prolific author was van der Fels-Klerx, HJ from Netherlands with 9 documents. He is active in the field of Food Quality. According to Scopus reports, his total products (126 records) received 4304 citations with 34 h-index. Wageningen University Research Centre with 27 documents (10.15%) was the most active affiliation in food supply chain risk assessment in the world. Distribution of the documents' affiliations is presented in Figure 2:9.

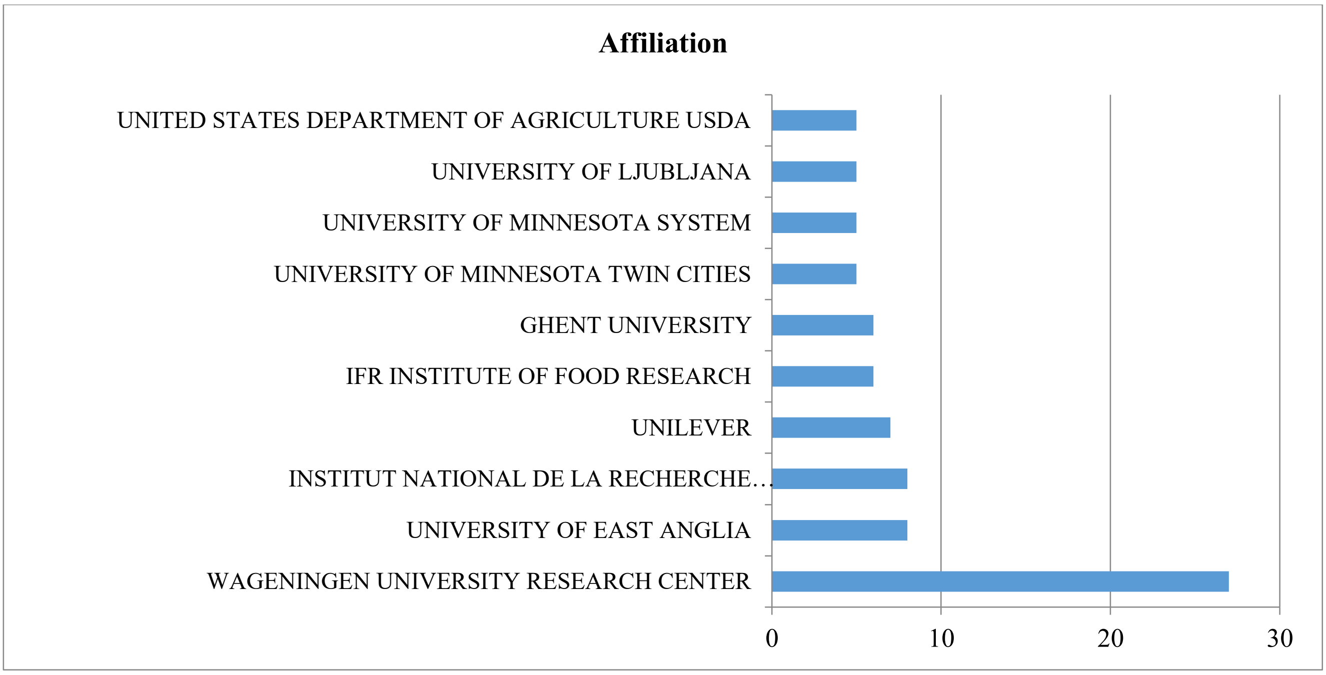

Figure 2:9: Distribution rate of food supply chain risk assessment publications based on their affiliation

Figure 2:10: Distribution rate of food supply chain risk assessment publications based on Subject area. A thematic analysis of the study results showed that the greatest number of documents belonged to Food Science Technology with 115 documents (35%) followed by Agriculture with 58 documents (17%), Business Economics with 38 documents (11%), Engineering with 26 documents (8%).

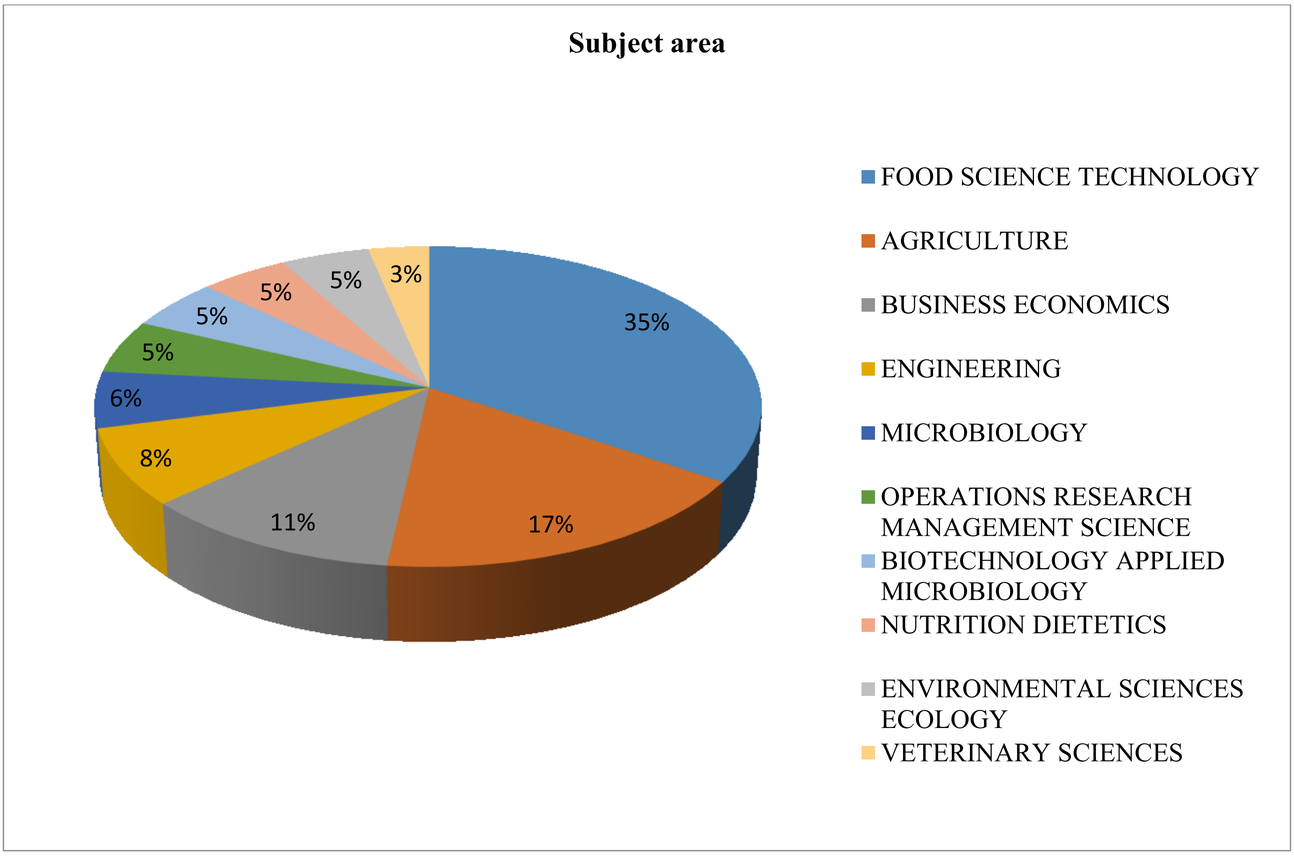

Figure 2:10: Distribution rate of food supply chain risk assessment publications based on Subject area

In order to identify the trends related to the citation analysis of food supply chain risk assessment, the necessary data were obtained based on the documents' publication years. According to the results, from early 1996 to 2014 (when the data were retrieved), the 266 documents had received a total of 3309 citations, implying an average of 174.16 citations per year and an average of 12.44 citations per document. Table 2:2 shows the most cited publications in food supply chain risk assessment.

Table 2:2: Citation analysis of food supply chain risk assessment

Row	Bibliographic information	Year	Author	Total citations	Average citations per year
1	Worldwide occurrence of mycotoxins in commodities feeds and feed ingredients. ANIMAL FEED SCIENCE AND TECHNOLOGY, 137(3-4), p 265-282.	2007	Binder, E. M.; Tan, L. M.; Chin, L. J.; et al	224	32
2	Emerging foodborne pathogens. INTERNATIONAL Journal Of Food Microbiology, 78(1-2), p 31-41.	2002	Tauxe	183	15.25
3	The Humboldt Current System of northern and central Chile. Oceanography And Marine Biology, 45(45), p 195-344.	2007	Thiel, Martin; Macaya, Erasmo C.; Acuna, Enzo; et al	180	25.71
4	Causation of Crohn's disease by Mycobacterium avium subspecies paratuberculosis. Canadian Journal Of Gastroenterology, 14(6), p 521-539.	2000	Hermon-Taylor, J; Bull, TJ; Sheridan, JM; et al.	149	10.64
5	Corporate social responsibility in the supply chain: An application in the food industry. JOURNAL OF BUSINESS ETHICS, 68(1), p 35-52.	2006	Maloni, Michael J.; Brown, Michael E.	131	21.83
6	The Belgian PCB/dioxin incident: Analysis of the food chain contamination and health risk evaluation. ENVIRONMENTAL RESEARCH, 88(1), p 1-18.	2002	Bernard, A; Broeckaert, F; De Poorter, G; et al.	107	8.91
7	Occurrence and Partitioning of Cadmium, Arsenic and Lead in Mine Impacted Paddy Rice: Hunan, China. ENVIRONMENTAL SCIENCE & TECHNOLOGY,43(3), p 637-642.	2009	Williams, Paul N.; Lei, Ming; Sun, Guoxin; et al.	93	18.8
8	Unraveling The Food Supply Chain: Strategic Insights From China And The 2007 Recalls. Journal Of Supply Chain Management, 44(1), p 22-39.	2008	Roth, Aleda V.; Tsay, Andy A.; Pullman, Madeleine E. et al	87	14.5
9	Ochratoxin A: Its cancer risk and potential for exposure. JOURNAL OF TOXICOLOGY AND ENVIRONMENTAL HEALTH-PART B-CRITICAL REVIEWS, 9(2-3), p 265-296.	2006	Clark, HA; Snedeker, SM.	81	10.125

The results highlight the multidisciplinary nature of food supply chain risk assessment. The greatest number of documents belonged to Food Science Technology with 115 documents (43.23%) followed by Agriculture with 58 documents (21.80%), Business Economics with 38 documents (14.28%). This results shows high contribution of these three disciplines (food science, agriculture, business economic), while, the contribution of the Engineering aspects are low with 26 documents (9.77%), that shows the limitation and research gap in the Engineering aspects of this topic.

2.2.5 Performance Measurement System (PMS) in SCM

Performance measurement (PM) in supply chain is a useful tool to provide feedback information for decision makers. Managers could be able to monitor performance, reveal progress, improve communication and motivation, and recognize problems in early stages. PM also reveals the effectiveness of strategies and identifies success and potential failure in the system. (Ramaa, Rangaswamy, & Subramanya, 2009)

With this regard, Holmberg (2000) defined the supply chain performance measurement as a system that provides a formal definition of supply chain performance based on mutually agreed goals, measures, methods that specify procedures of supply chain participants and regulators.

There has been numbers of studies on different range of performance measurement systems and performance indicators in the field of supply chain due to the need of developing integrated Performance Measurement System (PMS) (Gunasekaran & Kobu, 2007), specifically on strategic planning of supply chain and increasing supply chain performance in variety of aspects (Papakiriakopoulos & Pramatari, 2010), evaluating the performance of service providers in supply chain (Cho, Lee, Ahn, & Hwang, 2012), and supplier involvement for performance improvement (Estampe, Lamouri, Paris, & Brahim-Djelloul, 2013).

The study focusing on integrated PMS involving entire supply chain partners have been described in both quantitative and qualitative performance metrics by Gunasekaran and Kobu (2007). There are many studies regarding PMS that considered one section or function of the supply chain as Table 2:3 presents a summary of the performance indicators to be used for SCM based on these recent research.

Table 2:3: List of performance measurement for supply chain management

Supply Chain Process	Performance Measures	Author (year)
Plan	Order entry method Order lead-time	Gunasekaran, Patel, and McGaughey (2004)
Source	Supplier selection Buyer-supplier relationship	Hervani, Helms, and Sarkis (2005)
Manufacturing	Product cost, quality, speed of delivery, delivery reliability, flexibility	Ghalayini, Noble, and Crowe (1997)
Delivery	Delivery performance Number of faultless notes invoiced	Ghalayini et al. (1997)
Quality and customer satisfaction	Product quality	Aramyan, Oude Lansink, Van Der Vorst, and Van Kooten (2007)
Overall Chain	Total cost of inventory Information processing costs	Cook, VanSant, Stewart, and Adrian (1995)

In order to have an integrated PMS , the Supply Chain Council, have developed a unified model called SCOR model (Supply-chain operations reference-model) to identifying, evaluating and monitoring supply chain performance (Cuthbertson & Piotrowicz, 2008) and has been recognized as one of the well-established system that has been used widely in academic and practical environment (Benn Lawson, Squire, Burgess, Singh, & Koroglu, 2006). SCOR model includes performance in plan, sources, make, deliver, and return functions of supply chain, it has been adopted as a series of measures based on the sourcing function, overcoming competitive issues of modern supply chains, and evaluating the business and environmental performance of supply chain (Cucchiella et al., 2012). Number of different Supply Chain Performance Measurement (SCPM) models have been used by different authors, depend on their objectives of study and specification of measurement function. Each of these models have some advantages and disadvantages in application and results that are summarized in the Table 2:4.

Table 2:4: Pros & Cons of SCPM Framework

Author	SCPM Framework	Pros & Cons
Beamon (1999)	Supply chain processes	Pro: Identify three types of performance measures and propose flexibility quantitative measurement approach for supply chains Con: Lack of system thinking of measuring supply chain widely across the whole
Gunasekaran and Kobu (2007)	Decision making levels	Pro: Combine decision making levels with financial and non-financial criteria Con: Too many number of metrics and measures
Gunasekaran et al. (2004)	Decision making levels	Pro: Consider supply chain processes with respect to decision making levels Con: Need collaboration from all stakeholders of supply chain system to evaluate the framework
Aramyan et al. (2007)	Financial versus non-financial	Pro: Develop an integrated performance measurement system that contains financial as well as non-financial indicators Con: Investigate only single food company
Berrah and Clivillé (2007)	SCOR model	Pro: Use performance indicators from Gunasekaran et al. (2004) and apply MACBETH methodology to the supply chain processes Con: Does not consider the return process
Yeh-Yun Lin and Yi-Ching Chen (2007)	Six Sigma (DMAIC) processes	Pro: Propose a modified 2-tuple fuzzy linguistic computing (FLC) model to evaluate the performance of supply chain management Con: Lack of combining the decision making levels
Robb, Xie, and Arthanari (2008)	Operations practice and performance	Pro: Propose a model exploring operations practice and performance of supply chain management Con: Study only operations dimension, not for the whole supply chains
Chae (2009)	SCOR model	Pro: Offer a practical approach to performance measurement and propose key performance metrics Con: The return process is not consider in this work
Rodríguez et al (2009)	Balanced score card perspective	Pro: Propose the quantitative relationships performance measurement system based on the balanced scorecard Con: Study only one manufacturing company
Bigliardi and Bottani (2010)	Balanced score card perspective	Pro: Develop a balanced scorecard model for measuring performance in the food supply chain Con: Examine only specific industry field (the food industry)

Vorst, Beulens, Wit, and Beek (1998) studied the impact of Supply Chain Management on logistical performance indicators in food supply chains. They concluded, reduction or even elimination of uncertainties in order forecast, input data, and decision making process will improve the performance of the chain. Van Der Vorst (2006) analyzed the PMS in agri-food supply chain in terms of improving collaboration and transparency. They identified the fundamental role of traceability in improving cooperation and ultimate performance of supply chain in food industry.

To be more specific in food supply chain management and using PMS in this domain, there are a few literature focusing on the safety and quality aspects of food supply chain. Namely, Aramyan et al. (2007) developed a model for food supply chain performance measurement. In his model there are four groups of performance (i.e. efficiency, flexibility, responsiveness, and quality) and number of indicators for each group Figure 2:11. He claimed that specific characteristics of agri-food supply chains are mainly in food quality category that consists of product quality and process quality.

Product quality includes:

- Sensory properties and shelf life
- Product safety and health
- Product reliability and convenience

Process quality includes:

- Production system
- Environmental aspects
- Marketing

Product safety and health refers to food composition that must be free of hazards with an acceptable risk. Sensory perception of food refers to taste, odor, color, etc. Shelf life of product is defined by time between harvesting or processing and the time that it gets unacceptable for the consumption. And product reliability refers to compliance of product composition with product description.

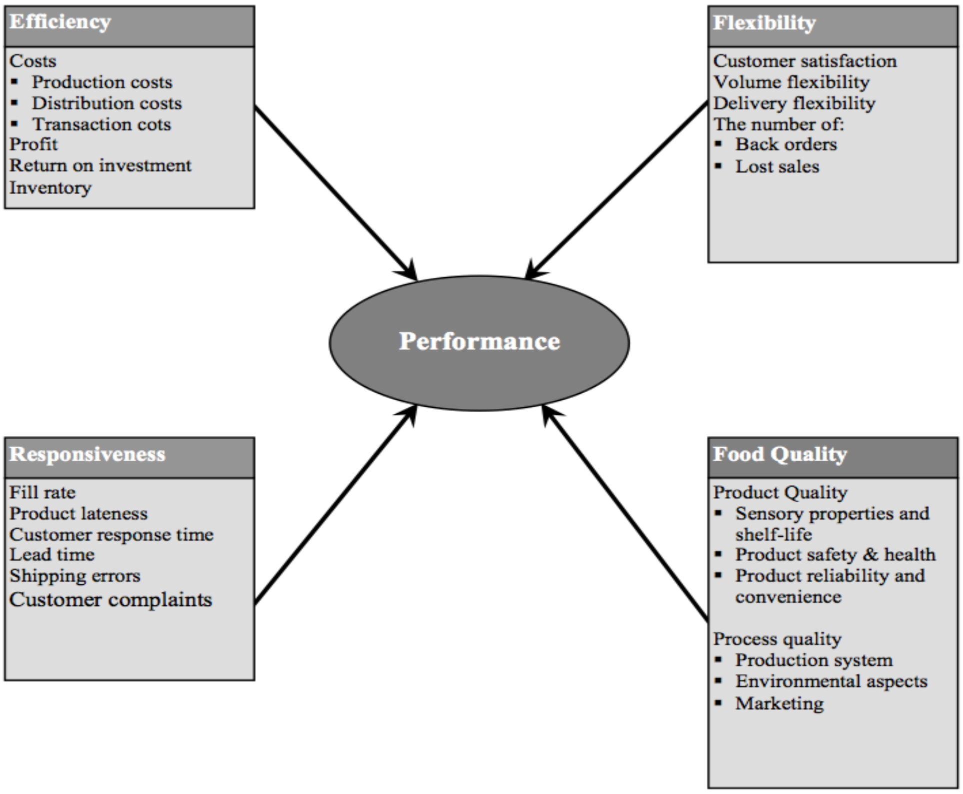

Figure 2:11: Framework of agri-food supply chain performance indicators. (Aramyan et al., 2007)

2.3 Food Safety Management System (FSMS)

As mentioned earlier, different food outbreaks have happened in Europe such as Listeria, Salmonella, E.coil, Mercury poisoning in fish, and Bovine Spongiforme Encephalopathy (BSE in 1996 and 2000), and they have made food safety as a public concern. (Constable et al., 2007)
In consequence, food quality has observed attentions, both in food safety and international trade, for public, policy makers, companies, researchers in an international level. Following this changes, a significant increase in public and private standards has emerged which has affected on food production, distribution and business. (Russo, Perito, & Di Fonzo, 2011)

2.3.1 Background of FSMS

Food safety is a key concept that, among all, contributes to food quality and different from other factors which effect on food quality. The reason is food safety has been thought as a public good and policy makers need to introduce and enforce mandatory regulation to be met by all parties involved. According to Constable et al. (2007), BSE was not the "first food scandal that affect food safety on European scale", but after the BSE crisis, regulations and legislations have reformed and new food safety authorities' institutions were established.

In fact, customers can evaluate the food quality through standards by improving the transparency and traceability of all processes including production, transportation and storage. Consumers are more interested to pay for products which have more information compare to those which do not. As argued by Motarjemi and Mortimore (2005), food and drink business is responsible not only for production of safe foods but also for transparency of how food safety has been planned and implemented, and this function is through the development of Food Safety Management System (FSMS).

The large number of food safety incidents in recent years and increasing the risk for public health has resulted in increased requirement for food safety and protection globally. EU regulation in this regards has evolved over the last 20 years in order to meet the growing demand of consumers within food safety. Nevertheless, food safety standards represent significant differences around the world. These standards are in both public level (i.e. Codex Alignments, regional countries, and individual nations) and private level (firms and supply chain demands and customers requirement), which both have different level of protections (Figure 2:12: Private and public food standards ,van der Meulen (2011).

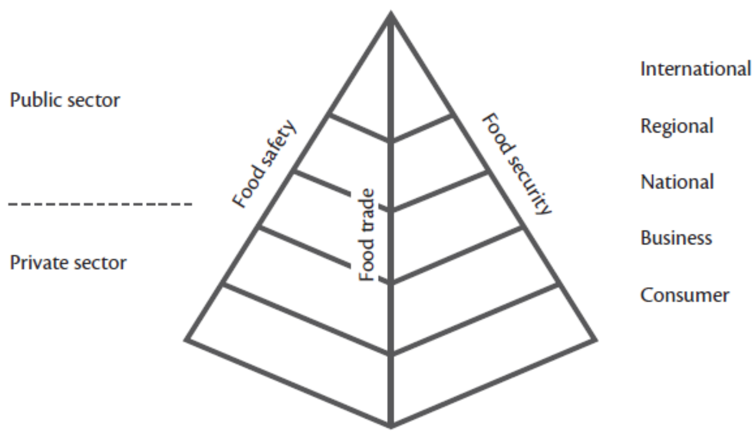

Figure 2:12: Private and public food standards ,van der Meulen (2011)

Private standards of the food quality control were built by numerous food organizations because of the need to additionally expand the safety of food to meet buyers' requests. As Luning, Devlieghere, and Verhé (2006) state, quality control frameworks have developed from simple investigation exercises (e.g. sorting, evaluating, corrective activities) to the highest amount of Total Quality Management (TQM) including such exercises as policy organization, involvement of suppliers, employees and clients, process administration, performance measurement, and so on. Food safety is connected to food quality and food safety is perceived as the fundamental basis and the principle-driving factor of food quality challenge (Luning et al., 2006). Other characteristic of food quality (Grunert, 2005) are shelf life of usability, food supplement, useful properties, organoleptic attributes, ecological perspectives, manageability issues, topographical issues, for example, controlled labels, and religious issues, for example, halal foods. In that regard, there is the reasonable call that food quality should no longer be connected with the product itself yet ought to be extended to the production process and that food safety must be coordinated into Quality Management Systems (QMS) (Grunert, 2005). QMS and, as a component of it, quality assurance systems and Food Safety Management Systems (FSMS) were set up to add to food security along the supply chain (Luning et al., 2006). However, the movement from third-party control towards control-of-control and standards require that QMS demonstrate their capability and methodologies. As mentioned by Van Der Vorst (2006) quality management in agri-food networks gets to be more integrated into Supply Chain Management (SCM). For example Brinkman and Hendrix (2011) demonstrate the requirement for SCM coordination and suggested an approach for coordination of QMS in food supply chain. This illustration depicts an innovative organization system including food safety and customer requests to be more integrated and uniform.

2.3.1.1 Application of Quality Management System

A certification from suppliers is needed by most European retailers in their supply chain, therefore, certification not only shows the qualification of product but also is a competitive advantage for the firms. Certification proves commitment to safe food production, and in in case of food outbreak legal protection for buyer-company is provided. The certificate likewise empowers the supplier to make and control the management system and to better meet the food quality and safety prerequisites as well as the legal compliance, particularly with respect to the legislations in the countries where final products are consumed. A certified producer can improve its safety performance by developing key features in the process, and reduce waste as well as products recall. As Færgemand (2008) states, utilizing the same strategies and methods for interpretation will make the integration with quality management system easier. Utilizing the same systems is more effective and improves food safety, boosts the utilization of resources and lower the risk of errors in procedure.

From January, 2006, the regulation in regards to food safety has been applied for companies in all of the European Union, by variety of European Commission (EC)-regulations. Food producing organizations are in charge of the safety of their produced foods. The producers should apply hygiene rules and guidelines and make control plans as indicated by the HACCP principles.

The most recent food safety regulation from the European Union put more emphasis on the safety of the consumers. The entire food supply chain in all nodes of suppliers, production, distribution and retailer have the safety responsibility according to (EC) 178/2002 "(EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety". (Sperber, 2005) (Article 17, paragraph 1) to meet the requirements stated in food legislation. Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP) and sanitation standard operational procedures, have been also considered among these prerequisites (Sampers, Toyofuku, Luning, Uyttendaele, & Jacxsens, 2012), they can be seen as foundations of HACCP and further towards approaches using food safety risk analysis. There are many requirements in the regulation for food producers, and the main goal of this legislation is to protect consumers from food hazards.

2.3.2 Food Safety Standards

Food safety deals with any issue related to hygiene and harmless of the food product; safe food needs to be free of contaminants that may cause a health threat, from this point of view food safety is an aspect of food quality (Luning et al., 2006) and it has become an important issue for food industry, politicians and customers.

Retailers in the food business, as other members of the food chain, need to follow the "due diligence" imposed by the legislation and authorities to meet food safety requirements. Besides, these companies have increasing concern about corporate social responsibility and brand reputation to get more market share, which also reinforce their food safety commitments (Escanciano & Santos-Vijande, 2014). Prior to the risk based approach in the food safety, food control followed a traditional procedure for many years which often includes many "do" and "don't" regulations. As described by Motarjemi and Mortimore (2005), these rules mostly rely on end-product inspections and testing. Also, these regulation vary country to country, for example in the UK there have many legislations like the Food Hygiene Regulation 1970 (HMSO, 1970) and the Food Act 1984 (HMSO, 1984) which relied on end product testing and their goal was controlling the risk by: firstly, controlling temperature related issues and specific standards for cross contamination, secondly, enforcement of trained detectors to investigate the points of possible risk (Wass, Marks, Finch, Leeks, & Ingram, 1997). Nevertheless, these kinds of risk based approaches were in efficient using many rules and standards that needed details attentions and usually leads to unsafe products.

To avoid any risk of hazardous product that could damage firm's private labels and brand image, retailers have set private quality standards and demand for suppliers to meet those requirements, usually by third party certification. In this regard, private food safety standards such as BRC (British Retail Consortium) and IFS (International Food Standard) have growth recently and became even more detailed and complex than government standard (Henson & Humphrey, 2009). In follow there are brief definition and scope of the main and well-known standards.

The BRC is the leading trade association for UK retailing. This standard set up in 1998 in response to industry requirements. The objective of BRC is based on food safety and quality management protocol according to HACCP and designed for manufactures of all types and food products. However, the standard does not apply to wholesale, importation, distribution and storage activities.

IFS (International Food Standard) was set up in 2002 by HDE (Hauptverband des Deutschen Einzelhandels) the German retail association. The IFS is a food safety and quality management protocol based on HACCP that is designed for producers of all kind of food products. IFS is applicable by retailers and manufacturing suppliers under the retailer responsibility. Similar to BRC, IFS is not dedicated to primary producers.

SQF (The Safe Quality Food) standard were originally set up by Western Australian Department of Agriculture in 1996. The main application was farming and small food manufacturing sectors for a quality assurance system. The SQF is designed for complete food safety management systems, however, comparing with BRC and IFS, it only specifies requirements of quality management systems and not good practice nor HACCP.

Dutch HACCP Code, was set up in 1996 by Dutch national Board of Experts-HACCP. This standard deals with all operators along the food chain (preparation, processing, manufacturing, packaging, storage, transportation, distribution, handling, and sale), but not suppliers or service providers for food business (e.g. supplier of packaging, equipment, cleaning). It is based on HACCP and quality management systems but not on good practices.

The Euro-Retailer Produce Association (EUREP) was established in 1997 by large European retail chains, and was joined by large fresh produce suppliers and producers. The EUREP has also developed EurepGAP, to promote good agricultural practices and regain consumer confidence in food safety, animal welfare, environmental protection and workers welfare. It encourages the minimal use of agrochemical, medicinal and has wider scope than food safety, so far as worker safety and health, environmental and animal welfare issues. The EurepGAP does not demand for implementation of a HACCP system, though it requires a risk assessment of different inputs at different stages (harvesting, transport, and handling).

In order to avoid overlapping in standards and to harmonize existing standards, ISO designed the standard for FSMS as ISO 22000:2005 "food safety management systems requirements for any organization in the food chain". (Færgemand, 2008)

In the Table 2:5 major certification for food safety is listed based on FAO 2006 report.

Table 2:5: Major certification for food safety (FAO, 2006)

	BRC Global Standard-Food	IFS	SQF	Dutch HACCP Code	Eurep GAP	ISO 22000
Geographical range	British market and Scandinavian market to a less extent	German and French market	American and Australian market	Dutch market	European market	International
Intended operators	Food Manufacturing	Food Manufacturing	Food primary producers/industries	All operators handling food	Primary producers	All operators handling food
Provisions scope	Quality management system+ HACCP +GMP	Quality management system +HACCP + GMP	Quality management system	Quality management system + HACCP	GMP	Quality management system + HACCP
Requirements	The majority of the UK retailers need RBC from their suppliers	German retailers need IFS from their suppliers	Many Australian and American retailers recognize SQF but it is not a requirement systematically	Not available	Some EU retailers require EurepGAP from their suppliers	Accepted by retailers and producers

2.3.2.1 ISO 22000:2005

ISO, the International Organization for Standardization, is an association developing number of standards for systems and processes in many different industries. 163 national standards organisations were member of the ISO organization in late 2010 and ISO´s portfolio have more than 18500 standards regarding economic, social and environmental developments (IFS, 2014). ISO 22000:2005 is a quality management system aiming in food safety in food production and can be connected to a wide range of companies in the food supply chain. Færgemand (2008) defines ISO 22000:2005, Food safety management systems: "...aims to ensure that there are no weak links in the food supply chain."
This is obtained by the adaptability of the design in the standard, which enables an approach appropriately customized for all sectors of food supply chain regarding the food safety. ISO 22000:2005 is intended to fit in distinctive approaches since the requirement of food safety varies among different sectors. The standard does not provide specific procedure or checklist, as process in one sector may not be the same as other sector.

In a statement done by IFS (International Featured Standards)
"Standards of product and process quality are an inevitable part of today's food-production landscape. In the global marketplace with international flows of goods, a verified standard has become indispensable." IFS (2014)

The food safety and quality standard IFS Food was made in 2002 for the private retailers and is today being used both for private and industrial retail companies. In the mission statement of IFS (2014) it is expressed that their central goal is to build up an umbrella brand for product safety. IFS have created norms for food safety as well as logistics, personal care, intermediaries and wholesale business. After the audit presenting IFS Food in a food production site, IFS permit a time of 12 months for correction activities. This is to give the organization enough time to take a shot and add to their methods according to the standard. Around the world, 12,000 companies are certified by IFS Food (IFS, 2014).
Applying international food standards is essential part in the firm's competitive advantage. Company social responsibility, consumer care, environmental standards are some of the requirements from food producers and industries (Djordjevic, Cockalo, & Bogetic, 2011). As argued by Djordjevic et al. (2011) companies' reasons to implement FSMS is quite different, and it has been analysed from different aspects in different firms' sector and countries.
As Escanciano and Santos-Vijande (2014) pointed out, while ISO 22000 is one of the food safety management standards, it is unique in its applicable that cover all steps of the food chain, from farm to

the table. The result of their survey on 189 Spanish firms with ISO 22000 certification showed that the internal and external motives for improving food safety management and obtaining competitive advantage are the main reasons for the selection of this standard when applying FSMS, and specifically improving efficiency, productivity, and quality are the major reasons.

2.3.2.2 HACCP (Hazard Analysis Critical Control Point)

The HACCP system was first created by an American organization for NASA in the 1960's since it was significance that the astronauts' food was totally safe during their journey in space. HACCP (Hazard Analysis Critical Control Point) is a framework used to control potential risks in food production and assures the safety of the food in the entire food chain (Panisello & Quantick, 2001).
The survey performed by Djekic et al. (2014) in three European cities (Belgrade, Thessaloniki and Porto), evaluated the level of hygiene in food retailers. 91 food companies were involved in this research and from 600 consumers; their perception of food safety and hygiene practice was investigated. This study proved HACCP as an important concept and food establishments have different level of hygiene based on their HACCP status but not the size and type of firms. HACCP is included in almost all of the standards mentioned in Table 2:5, as per regulation (EC) 852/2004 article 5, 7 and 8, food producers are obliged to follow the HACCP standards in the food producing. Additionally regulation (EC) 178/2002 article 3.7, 3.9, 3.14 and article 14 of food safety necessities and regulation (EC) 853/2004 states that HACCP must be connected in all food production. (Ying et al., 2014)
There are many research focusing on Hazard Analysis Critical Control Point (HACCP), and limited number of study referring on ISO 22000 specifically (Trienekens & Zuurbier, 2008). The reason behinds implementation of HACCP by the firms, among others, are improving safety and quality of the products, getting more market share, having better company's image, and external pressures.
The motivation behind HACCP is to produce safe food and to prevent hazards identified with food hygiene during production and processing. There are various types of health hazards identified with food hygiene; microbiological, chemical, physical, and allergens. The microbiological hazards could be moulds, viruses or bacteria that causes disease for instance through development of toxins, the physical hazard happens if foreign objects like glass or plastic enters to the products. If the cleaning materials or different chemicals utilized as a part of cleaning or support of the production line gets into the food it is a chemical hazard, allergens like milk or nuts could be allergen hazards if found in foods where they are not belong to. The HACCP-framework concentrates on the quality and safety of the food itself and do not cover other quality issues of the organization. A quality management system, in the same way as ISO 9001, covers in general around all quality parts of the organization.

HACCP is incorporated into quality management systems as an instrument to find and control factors and methods that deviates from the quality with respect to food hygiene hazards. As indicated by Codex Alimentarius on Food hygiene (1997) the HACCP system comprise of seven principles:

- Conduct a hazard analysis.
- Determine the Critical Control Points (CCPs).
- Establish critical limit(s).
- Establish a system to monitor control of the CCP.
- Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
- Establish procedures for verification to confirm that the HACCP system is working effectively.
- Establish documentation concerning all procedures and records appropriate to these principles and their application.

These seven points are the fundamental goals of HACCP which principle reason for existing is to ensure the production of safe food, free from microorganisms creating sickness, allergens, foreign objects and safety risk substances. HACCP is a prerequisite for all food productions by the regulation from 2006 (EC) 852/2. 852/2004, article 5. (FAO, 2006)

Principle 1, Conduct a Hazard Analysis, among others, act as a central pillar of any HACCP since hazards need to be identified and analysed before control measures can be determined. Codex Alimentarius (2009) represents some brief elements to consider for hazard analysis principle 1 that are as follow:

The HACCP team need to list all potential hazards expected to occur in each step of the production, processing, manufacturing and distribution of the food to the point of consumption.

The HACCP team then should conduct a hazard analysis to identify which hazards could be eliminated or reduced to acceptable levels for the production of the safe food considering following points:

- The probability and severity of the occurrence of hazards
- The qualitative or quantitative evaluation of the hazards
- Survival or multiplication of microorganisms
- Production or persistence in foods of toxins, chemicals or physical agents

Considering to what control measures can be applied for each hazard, one or more control measures may be required. To identify the hazard which are significant for food safety, Codex Alimentarius (2009) has the following definition:

Hazard:
A biological, chemical or physical agent in, or condition of food with the potential to cause an adverse health effect.

Significant Hazard:
Hazard that are of such nature that their elimination or reduction to an acceptable level is essential to the production of safe foods.

Hazard analysis:
The process of collecting and evaluating information on hazard and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in HACCP plan.

HACCP is a food safety management system and is widely accepted as the best tool of ensuring food safety as well as worldwide recognized method for controlling food born hazards. (CAC, 2011) However, correct implementation of the HACCP plan is essential in the success and effectiveness in preventing food safety risks and reducing food borne diseases (FAO/WHO, 2011). Moreover, there have been many issues and barriers in implementation and application of the food standards mentioned in literature that are discussed in the next section (2.3.2.3) with details.

2.3.2.3 Issues for Standards

Lots of the data in regards to standards and certifications originate from the certification associations or from authorisation organizations. Subsequently these data is regularly in one side positive, yet there are some negative angles in regards to certificates as well. One of them is the phenomenon of 'soft grading', which implies that when an organization is obliged to execute a standard because of a requirement from a client they may pick the most convenient approach to gain the certificate. This weakens the validity of the standard and prepares for less genuine certification structures.
Standards can be obstructions to business however they can likewise be incentives to trade (Lusk, 2011). Depending upon a variety of variables there is a danger of both "under" or 'over-standardisation' when a food producer apply a standard in their process. This is one of the motivations to the current requirement for controls made by a third party who implement and authorizes standards in food production. (Lusk, 2011)
Numerous retail organizations oblige that their supplier must have a standard in the production. In an investigation of food production by Henson and Reardon (2005) this is seen as a negative advancement

because of the double expenses and reviews. A significant number of the food production in the study considered the supervision done by standards bodies and controllers very much alike. They argued that food producers might need to experience several audits based on various standards since there are no global standard for food safety risks.

Various diverse types for quality control exist, the most common in the connection of food quality and food safety is Good Manufacturing Practice (GMP), ISO– Classifications and Hazard Analysis Critical Control Points (HACCP). All of these ideas are proposed to control food safety and have in common that they are expand upon fundamental hygiene practice and that they cover preventive measures. This is particularly valid for HACCP, which is sometimes wrongly introduced as a separate preventive instrument in food safety. Rather, HACCP has essential hygiene requirements, presence of a secured cleanliness environment, accessibility of effective controlling and reliable checking are preconditions before HACCP can be executed. Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP) and Good Agriculture Practice (GAP), can be viewed as transformative antecedents of HACCP and further towards methodologies utilizing food safety risk analysis. (FAO, 2006)

HACCP has been effectively extended from its starting point in the processing step to primary production and food manufacture (Vilar et al., 2012). It is stated that (Somers, Frankena, Noordhuizen-Stassen, & Metz, 2005) "food safety, public health, and animal health ought to be incorporated into one HACCP-based system". On the other hand, a few firm use the procedure for "HACCP at farm level", due to the fact that hazards are not clearly defined and characterized, and that most hazards are typically controlled at a later point in the food chain since the farmer needs possessions and ability to plan and apply HACCP program and also due to an absence of GAP/GHP preconditions (Heggum, 2001).

2.3.3 Human Factor and Behavioral Perspective in Food Safety

More and more often safety managers in worldwide companies are considering human factors in safety analyses. This is due to the fact that in the most cases human factor error has been realized as the cause of unwanted events. However foreseen human behaviour especially during every day work is a nontrivial task (Colombo & Demichela, 2008).

Systematic measures must provide reliable outcomes and to guarantee the reliability of systematic measures and procedures, e.g. safety control of food, it is essential to validate these measurement processes. This procedure validation often covers technical and machinery aspects, while the important role of human factors in this procedure is often neglected. Kieffer (1998) disputes that: “Frequently the steps in the process which involve human factors intervention are the weak links in the process and quite often in validation work the human factors element is ignored while mechanical and technological aspects are studied in great detail". Similar to other industries, within the food safety procedure, this issue is tangible as well, and it might originate from the fact that technical and instrumental aspects are covered by the HACCP in more details comparing to the human factors. Risk analysis can bridge that gap, but up to now few results have been presented in which the human factors is fully taken into account in the food risk management. (Colombo & Demichela, 2008)

For this reason many researchers started to work on human and organization issues. To determine the human factors influence on safety, within European Community, Innovation thought Human Factors in Risk Analysis and Management (InnHF) project has been established. Within the food safety field of research, there are very few studies considering the role of human factors and its effects on the final product and consumers' health, while most of the food process operations and controls perform by human. There are limited studies on human factors behaviour in food safety control (Liu & Wang, 2011), HACCP implementation (Milios, Drosinos, & Zoiopoulos, 2012) or food hygiene practice and human factors errors in water incidents (Wu et al., 2009). However, analysing the human or organization failure in a general perspective and more scientific approach (risk assessment) is lacking within the food safety literature and food industry as well. Therefore, in this study aims to cover also human factor in food safety risk management approach, and analyses its influence on the final product safety.

Management of safety has always been based on underlying models or theories of organization, human behaviour and system safety. In most complex interactive systems, human error can lead to critical system failures. Experience also demonstrates that human contribution can be very effective in safety issues if the proper culture of risk management and safety exist within the organizations. Moreover, an efficient interaction of human and machine is essential to avoid human errors and also assist the operator to overcome the unforeseen issues (Reiman & Rollenhagen, 2011).

Despite the fact that machines replace role of human, human makes design and control of machines. Thus, the majority of the safety issues ought to be attributed to human variables. Because of the subjective decision-making and limited rationality, human practices do not always precisely follow the instructions, however they are more or less twisted by personal reasons.

Risky components of food supply can be found in different places in food supply chain. They can exist in supplying connection, in production, in transporting, or in consumer connection. These hidden issues for the most part owe to human practices. Individuals are key in the food supply chain, for the food production network is run just by various types of human exercises. On the other hand, because of the limitation of perceptions, human may not always behave right, which prompts distinction between behaviours and expectations, and cause food safety issues. (Mela, 1999) Each member in food supply chain behaves differently; even one individual acts distinctively in a different time period. These differences of human behaviour increase uncertainty to the networks. Hence, human behaviour is one of basic components that effect the food supply chain safety, and preventing and controlling food safety hazards from a behavioural aspects is turning into urgent practical issue that needs be overcome.

Concerning explores in supply chain of food, Li et al. (2012) examined the reasons of farmers' being careless and practical tendency, furthermore the impacts of uncompleted contracts and supervision barriers on farmers' agreement. Jiang Shapiro, Porticella, Jiang, and Gravani (2011) investigated public perception of food safety risk, amid which the impact of human behaviour on risk perception was examined from the perspective of both individual and public. Amaratunga et al. (2010) introduced a performance measurement system, to motivate managers to perform value adding operation plans for corporate qualities.

Behaviour is a psychological concept that contains four elements that are values, attitudes, perception, and learning (Cox & Cox, 1991). Attitude is an essential one, as its affecting factors are less demanding to be discovered and get controlled. Different persons may hold distinctive attitudes for the same thing, the same action or the same individual, so they act in distinctive ways. Attitude is not natural, however shaped slowly during the interaction with other individuals, groups and environment. There are numbers of factors that impact the structuring of attitude: the need, the knowledge, the group cognition, the individual personality and the individual experience. (Guldenmund, 2000)

Attitude impact the behaviour, however, the act of a behaviour needs motivators. Motivating force is a psychological action that natural inspirations, which makes individuals, endeavour to their objective. The motivation procedure is begun in an external boost, which rises up out of the incompatibility of individual and the environment due to an imbalance or unreliability, then the feeling starts to get nervous, and this pressure is a performance of need. The need is another impact of attitude. When the external motivation can meet the needs, then the motive will happen and behaviour will follow. When the behaviour meets the need, then tension will be lower and subsequently the entire procedure of motivation will be finished. (Cox & Cox, 1991) This shows that human behaviour is an essential part in food safety control. Those behaviours that cause risks are considered as "unsafe behaviour". In order to prevent unsafe behaviours, the attitude- forming factors and incentive factors needs to be changed to control the attitude and the incentive, therefore, the behaviours of human in food supply chain will be directed towards food safety goal.

2.3.3.1 Food Safety Culture and Education

The concept of safety culture is taken from organizational culture with specific application to one aspect of business activities, which is the safety of staff working within the business or people who are in contact with its product or service.

The phenomena of safety culture became more popular since the Chernobyl in 1986 and gained more attentions within academics and industries (Wiegmann, Zhang, Von Thaden, Sharma, & Gibbons, 2004). Since then it has been studied from different aspects, such as aviation, nuclear power and healthcare, and it has been defined in different ways by researchers. For example, The Confederation of British Industry (CBI, 1991) defined safety culture as, "the ideas and beliefs that all members of the organisation share about risk, accidents and ill health". Whereas, Eiff (1999) mentions "safety culture exists within an organization where each employee, regardless of their position, assumes an active role in error prevention and that role is supported by the organization".

In support of safety management system, Guldenmund (2000) pointed out that a culture based on appropriate experience and knowledge is necessary to support safety management system and changing a high risk system to a high reliable one. It can be specifically applied in the food industry when the life of consumers are in hands of food companies in sense of food poisoning, and for this reason food safety should be the main priority morally and financially in this industry.

However, the current food safety culture deals with improving the food safety handling by integration of safety management system and workforce behaviours, beliefs and values to decrease the risk of food borne hazards (Griffith, Livesey, & Clayton, 2010). In support of this idea Yiannas (2009) believes that it would be better if the firms focus more on efficient food safety culture rather safety system. He also stated that firms can create an efficient and strong safety culture by leaders' commitment due to their power and effect on employees' behaviours, beliefs and values.

The summarizing of the safety culture definitions from different perspectives by Griffith et al. (2010) provides following points applicable in the food industry:

- It defines shared beliefs of the organizations' staff
- All people from different level in a firm need to be involved
- It effects on staff's behaviour, norms and performance
- It includes a range of values, attitudes and beliefs which are relatively constant and might be difficult to change
- It can be communicated and learned by new employees
- Any organization could have several subcultures
- An organization can have deferent food safety cultures in different levels, mostly in larger firms.

The knowledge and information people get in working or training environment impact the shaping of attitudes. They have a tendency to compare the knowledge they recently receive to their current attitude, and change previous cognition to develop new attitude through new learning. Some food supply chain members have lack of proper knowledge or perform deviated operations, which brings about safety issues. By training and preparing, attention of food safety or practice of safe operation, employed staff could get their knowledge improved, and behaviours controlled.

Roberts et al. (2008) dissected the behaviour oriented food safety training, finding that after individuals went to food safety practices training which stressed on right practices, they behaviours changed and lastly developed into habits. As a result, in preventing and controlling food supply chain safety risks, food associations need to play an active part in related training. These training needs to be in all nodes of supply chain from upstream (suppliers, agricultures, forestry, etc.) to downstream (retailers, restaurants, transporters, etc.). For instance, workers in upstream supply chain ought to get related training and preparing regarding pesticide and farming chemicals use, poultry food and so forth. Through training and preparing, food suppliers can improve their insight approach for on-going safety issues in day by day operation, in this way the likelihood of food supply chain safety risk could decrease by reducing unsafe behaviour.

2.3.4 Preventive Approaches in Food Safety

Outbreaks in the agri-food network are recognised due to four separate reasons: animal illnesses, operational deviation, natural disasters and terrorist attacks. These reasons can be further classified by what kind of processes are the main areas for prevention: natural and biological, technical and managerial, decision-making and communication processes (Cheftel, 2011).

For the further illustration it is important to make a difference between the terms prevention and control because these two firms are used in wide definition in literature. Control as the general term signifies "prevention, elimination, or reduction of hazards and/or minimization of risks" (CAC, 2011). In some contexts preventive and control are simply utilized as a pair of terms to emphasize an ideal model, change from traditional end product quality control towards more current anticipatory ideas (Burlingame & Pineiro, 2007) or the term preventive is basically utilized for everything that is by all accounts helps food safety regardless of its connection to the concept.

The term preventive measures infer the presence of basically executable measures (e.g. washing hands) performed by an individual (e.g. dairy agriculturist) yet a few measures are long term in nature and the impact is not directed to action (e.g. storage of feeding in closed environment). Most measures are related to a structural and organizational sections that vary enormously with respect to hazard reduction, reliability, costs, and responsibility. A few measures are absolutely technological process (e.g. pasteurization) while others are more administrative process (e.g. selection of transportation mode). Thus,

food quality as a function of the food behaviour and human behaviour, managerial aspects only impact prevention indirectly and not covered by the term preventive measures.
The term preventive can be looked upon from several perspectives. From a temporal perspective measures are viewed as preventive in the event that they happen before the identification of the problem. In this point of view, the intervention is not possible until the pathogen is known. The main goal of epidemiology is to recognize the connection between risk factors and results as food outbreak. From an epidemiological point of view actions are considered preventive if they are capable to decrease the result of a known risk factor or to eliminate that risk factor. Regarding the temporal perspective, in the disease outbreak, only measures that aim to decrease the spread of disease are called intervention measures. (Pfeiffer, 2010)
Preventive measures requires a great deal of prior data comparing with intervention methods. It must be supported by creating database and communication systems to coordinate private and public systems. With this respect, risk assessment has been a powerful tool in preventive measures and achieving safety in variety of industries. Using risk assessment within the food safety domain is an emerging method which is discussed in the section (2.4).

2.4 Food Safety Risk Assessment

Food safety is a vital public health concern, and achieving a safe food poses major challenges for national food safety officials. Food-borne hazards pose risks to health and obstacles to international trade in foods. These risks must be assessed and managed to meet growing and increasingly complex sets of national objectives. Risk analysis, a systematic, disciplined approach for making food safety decisions developed primarily in the last two decades.

2.4.1 Background

Every organization with various types and sizes face many kinds of risks that may affect achieving of organization's goals. These goals might be related to a broad variety of their activities, from strategic of processes, and operations. It might be in the field of technological, environmental, economic and financial measures, safety and security of products, in addition to cultural, political, and social influences.
Based on ISO 31000 (2009), the risk management can help decision-making process by considering the uncertainty and possibility of prospective outcomes and events (intended or unintended) and probable influences on the organization's goals. Risk management consists the applying of logical and systematic

strategies for communicating and consulting in the process. It is also helpful for providing the context for recognizing, analyzing and evaluating treating risks related to activities, processes, functions or products, monitoring and reviewing risks, as well as, reporting and reordering the results accordingly.

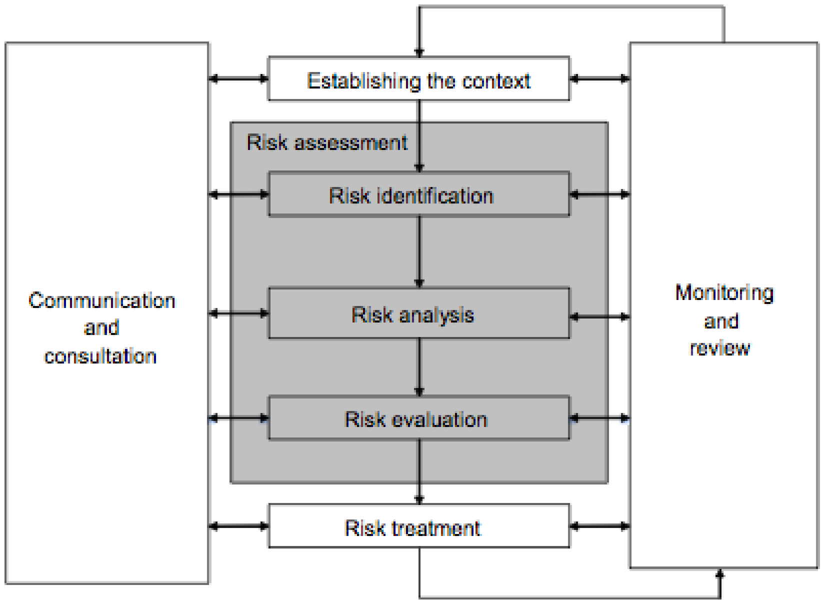

Figure 2:13: Risk assessment procedure based on ISO 31000 (2009)

Risk assessment is the core part of risk management which provides a structured process that identifies how objectives may be affected, and analyses the risk in term of consequences and their probabilities before deciding on whether further treatment is required.

Risk assessment attempts to answer the following fundamental questions:

- What can happen and why (by risk identification)?
- What are the consequences?
- What is the probability of their future occurrence?
- Are there any factors that mitigate the consequence of the risk or that reduce the probability of the risk?

On the other hand in the report provided by FAO/WHO (2011) for food safety risk management, the components have slightly different definitions, however, the concept and logic is constant with ISO 31000 standard. According to FAO & WTO (FAO/WHO, 2011) , Risk analysis is used to estimate the risks of food on human health and safety, to develop and apply proper measures to control the risks, and to communicate it with stakeholders. It also can be used to improve and support the development of standards, as well as to address food safety problems that consequence from emerging hazards or issues in food control systems. It facilitates the effective decision-making for the food safety regulators and authorities by providing the required information and evidence, contributing to significant gains in food safety and enhancements in public health.

Moreover, the risk analysis process enables involved parties to recognize the various control points along the food supply chain at which measures could be applied, to compare the costs and benefits of different alternatives, and to select the most effective one(s). As such, it provides a method to consider the probability effect of the possible measures and contributes towards better utilization of public resources by focusing on the highest food safety risks.

Component of the risk analysis according to FAO & WTO (see Figure 2:14) are risk management, risk assessment and risk communication.

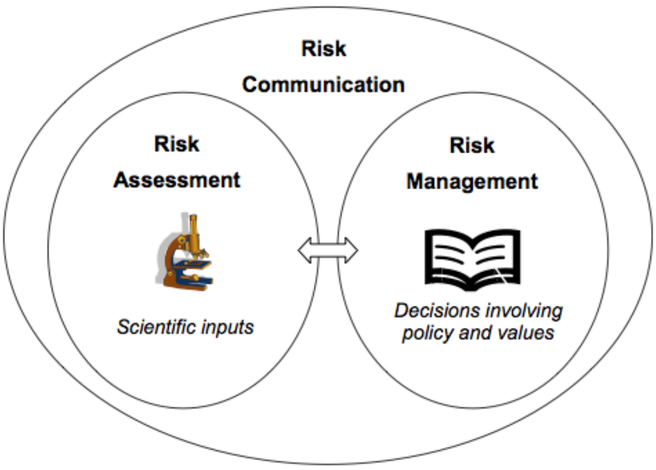

Figure 2:14: General components of risk analysis based on FAO/WHO (2011)

These three components are highly integrated, although in the figure they have different entities. The constant interaction between risk assessors and risk managers are essential in the environment of the risk communication. The three main components of risk analysis have been defined by Codex as follows.

Risk assessment: A scientifically based process consisting of the following steps: i. Hazard identification; ii. Hazard characterization; iii. Exposure assessment; and iv. Risk characterization.

Risk management: The process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

Risk communication: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

2.4.2 Risk Assessment

According to ISO 31000 standard (2009), risk assessment is a "science-based" part of risk management in which scientific information and other elements include, for example, social, cultural and ethical issues, are combined and weighed in choosing the convenient risk management options.

Specifically, those perform risk assessments have to be informed about:

- The context and objectives of the organization,
- The extent and type of risks that are tolerable, and how unacceptable risks are to be treated,
- How risk assessment integrates into organizational processes,
- Methods and techniques to be used for risk assessment, and their contribution to the risk management process,
- Accountability, responsibility and authority for performing risk assessment,
- Resources available to carry out risk assessment,
- How the risk assessment will be reported and reviewed.

Risk assessment is totally the process of risk identification, analysis and evaluation. Risk assessments can be performed at various levels such as at organizational or departmental levels, for projects, individual activities, as well as, distinct risks. Various tools and methodologies may be helpful in particular contexts. Risk assessment declares a figuring out of risks, the reasons, outcomes and probabilities which would contribute to decisions by providing inputs about:

- Whether an activity should be undertaken;
- How to maximize opportunities;
- Whether risks need to be treated;

- Choosing between options with different risks;
- Prioritizing risk treatment options;
- The most appropriate selection of risk treatment strategies that will bring adverse risks to a tolerable level.

As the risks may include a broad range of causes and consequences, then, a multidisciplinary approach may be needed for risk assessment. In the food safety domain, risk assessment might have a marginally separate definition and procedure structure, but, the overall principal of the logic and outcome is similar to risk assessment techniques introduced by ISO 31000 standards. Codex explained four analytical steps in risk assessment (see Figure 2:13), which would be particularly addressed in the next section. The way of implementing these steps might be to some extent different for chemical or microbiological hazards.

2.4.2.1 Risk assessment in the food industry

Hazards that are a focus of food safety control deals with risks on customer safety, animal health, economy and the general public. This risk depends mainly on the degree of injury and the likelihood of occurrence (Lammerding & Fazil, 2000). An evaluation of this risk is important to support the decision-making with respect to administration and regulation. Risk assessment is the scientific foundation for every further steps of risk analysis, i.e. risk management and risk communication (Codex Alimentarius Commission (1999).

CAC and EU characterize hazard analysis as the general term that joins secondary tasks of risk assessment, risk management and risk communications. Risk assessment is further grouped into hazard identification, exposure assessment, hazard characterization and risk characterization. This scheme has turned into an integral section of the EU food hygiene legislation and was introduced by World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (Scott, 2007) which obliges that all protective measure must be risk based. It should be mentioned that in the field of business administration (ISO 31000 standards) and quality management risk management is viewed as the more general term, which comprises of risk identification, risk assessment and risk control.

The outcome of the risk assessment is used as an input in risk management, i.e. to select, recommend, or develop an appropriate control measures (prevention or intervention). For the risk management objective the outcome of the risk assessment needs to be transferred into legislation, regulation, or operation procedure in concepts like HACCP, GHP, GAP, etc. This transferring the outcome from risk assessment to risk management is quite a challenging task in practice.

Different risk assessment methods are used in different countries and within countries, and different methods may be used to assess different kinds of food safety problems (Table 2:6). Methods vary according to the class of hazard (i.e. chemical, biological or physical hazard), the food safety scenario (e.g. concerning known hazards, emerging hazards, new technologies such as biotechnology, complex hazard pathways such as for antimicrobial resistance) and the time and resources available.

Table 2:6: Characteristics of biological and chemical hazards that impact on risk assessment method selection (ISO31000 ISO, 2009)

Biological Hazard	Chemical Hazard
Hazards can occur at many point along the food supply chain	Hazards usually occur in the raw materials and ingredients, or certain processing steps (e.g. packaging migrants)
The concentration of hazards change at different points along the food supply chain	The level of hazards present in a food after occurrences often does not change significantly
Health risks are usually results from a single portion of food	Health risks may be acute but are generally chronic
Individuals have wide variability in health response to different levels of hazards	Types of toxic effects are generally similar from person to person

In biological and microbiological hazards, the hazards can occur and transmit in different nodes of supply chain, from supplier to consumer. Thus, it is required to move forward along the various stages of food chain to evaluate the estimation of risk. Although the accuracy of estimated risks is often limited by uncertain dose-response data, the most advantage of such risk assessments lies in their ability to model the relative influences of distinctive food control measures on risk estimates.

In chemical hazards, by contrast, “safety evaluation” is a standard risk assessment methodology. In this method, maximum exposure levels (a dose level that is certain to pose no considerable risk to the consumer) are recognized to meet a “notional zero risk” consequence. However, this method does not support precise estimates of risk versus dose and cannot model the impact of various interventions in terms of risk reduction.

2.4.3 Basic components of a risk assessment

Food safety risk assessment deals with identifying which foods, hazards or circumstances result in foodborne disease and the severity of this effect on human health. Thus, the risk of food borne illness is made on two elements; the probability of exposure to a hazard in a food product, the probability of that exposure will lead to infection or intoxication or illness and the severity of the disease. Accordingly, risk assessment is a science based process that estimates the probability and effect of adverse health impact and involves four steps: hazard identification, exposure assessment, hazard characteristics and risk characteristics (Figure 2:15)

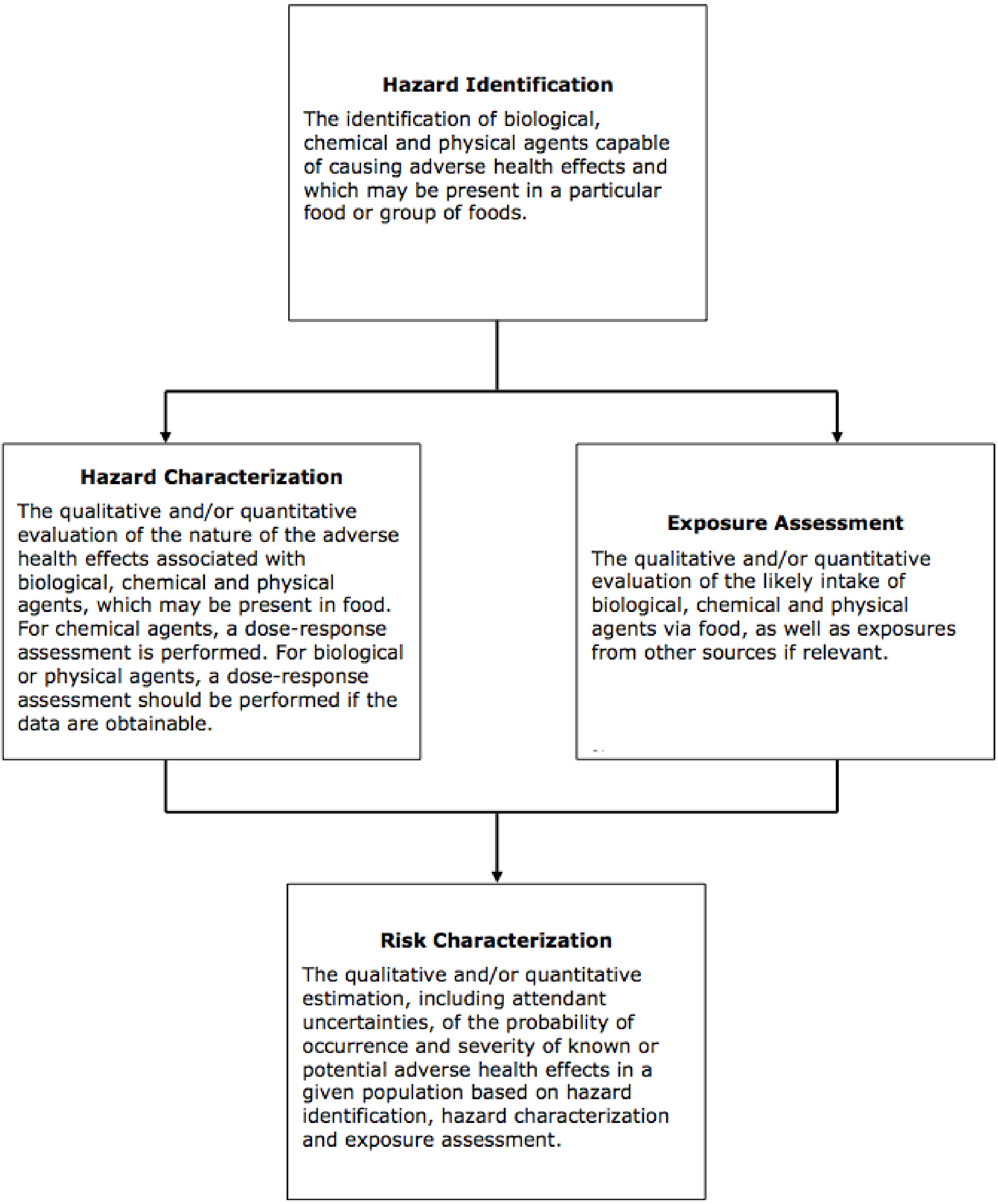

Figure 2:15: Generic codex description of the components of risk assessment (FAO/WHO, 2011)

2.4.3.1 Hazard Identification (or Risk identification)

Risk identification is the process of finding, recognizing and recording risks, as can be observed in ISO 31000 (2009). Identifying probable circumstances which might influence the attaining of the goals of system or organization is the objective of risk identification. The organization should recognize any current controls include, for example, design characteristics, individuals, processes and systems upon a risk are detected.

The risk detection methods consists of recognizing the reasons and origins of the risk (hazard in the context of physical harm), events, situations or occasions which might have a material influence on the goals considering the various aspects of the influence.

Risk detection processes can consist of:

- evidence based methods, examples of which are check-lists and reviews of historical data;
- systematic team approaches where a team of experts follow a systematic process to identify risks by means of a structured set of prompts or questions;
- Inductive reasoning techniques such as HAZOP.

In order to improve accuracy and integrity in risk recognizing, diverse helpful methods can be applied, consisting brainstorming and Delphi technique. Regardless of the certain methodologies applied, due recognition is given to human and organizational factors would be crucial during risk identification. Therefore, the deviation from what is expected of human and organizational factors, as well as "hardware" or "software" events should be considered in the procedure of risk identification.

FAO (2011) reports provided a list of major food-borne hazards that may occur in the food products (Table 2:7). Numbers of these hazards are well known and have been addressed by food safety controls, however, changes in the global context may alter these problems. Different classes of hazards have variety of characteristics which need somewhat different approaches to risk analysis. For instance the chemical hazards, specifically those that can be strictly controlled in the food supply such as veterinary drugs, residues of crop pesticides, and food additives have historically been subject to a "notional zero-risk approach". On the other hand, microbiological hazards are usually living organisms that are able to grow or reduce in foods and environment. They may need a different risk assessment approach and management method to keep risks within tolerable limits, rather than to remove them completely.

Table 2:7: Examples of hazards that may occur in foods

Biological hazards	Chemical hazards	Physical hazards
• Infectious bacteria • Toxin producing organisms • Molds • Viruses • Prions	• Naturally occurring toxins • Food additives • Pesticide residues • Veterinary drug residues • Environmental contaminants • Chemical contaminants from packaging	• Metal • Glass • Stones • Bone chips

CAC (2011) points out that food safety hazards is “a biological, chemical or physical agent in, or condition of food with the potential to cause an adverse health effect”.

In more traditional risk assessment, e.g., toxicology or environmental health the main focus is determining a substance (e.g. chemical) leading to adverse health effect (e.g. Cancer). However, in microbial risk assessment the hazard is usually already identified being able of causing illness even before initiating risk assessment. The cause and effect relationship for microbial hazard is often in shorter time period (days and week) but chemical hazard is usually measured in period of years. The short time phase for the cause-and-effect relationship in a food pathogen, lead to larger probability for an adverse effect exposed in a population. Thus it provides a positive evidence for a cause-and-effect relationship in biological hazards. Hazard identification in food risk assessment is mainly concerned with defining the main sources of exposure to the pathogen or chemical, and recognizing which hazards might be considered in specific food group. This information could be obtained from epidemiological investigations of foodborne hazards, and events that could lead to foodborne outbreaks, as well as surveillance studies that help to identify high-risk products or processes.

2.4.3.2 Risk analysis

Risk analysis is a developing and explanation of the risk according to ISO 3100. It would provide the required inputs for risk assessment and decisions, in order to determine whether the risks should be treated or the most convenient modification methods and strategies. Risk analysis include recognizing the consequences of identified risk events and their probabilities, considering the presence (or not) and the efficiency of any current controls. Afterwards, the consequences and their probabilities would be combined in order to calculate the level of risk.

Risk analysis consists of the considerations of the causes and origin of risks, their consequences as well as occurrence probability. The factors that might affect the consequences and probability should be determined. An event can have various consequences and influence diverse objectives. Several techniques for these analyses have been explained in Appendix 8.1 (Risk assessment tools (ISO 31000)) and it might be needed to apply to apply more than one method in complicated circumstances.

Techniques applied in analyzing risks can be qualitative, semi-quantitative or quantitative. The amount of details needed is correspondent to the special application, the availability of reliable information and decision-making requirements of the organization. Legislators may prescribe some techniques and the level of details of the analysis. Using significance level of risk include, for example, " high", "medium" and " low", qualitative assessment explains consequence and level of risk. It may combine the consequence and probability to evaluate the level of risk with regard to qualitative criteria.

Semi-quantitative techniques apply numerical rating scales for determining the consequences and probability in order to combine them for generating a degree of risk considering a formula. The formula applied can be various and the scales may be linear or logarithmic or have other relationships.

Quantitative analysis predicts possible values for consequences and their probabilities. It also provides values for the degree of risk in particular units explained by developing the context. Full quantitative analysis may not be always attainable or convenient due to lack of data about the system or activity being analyzed, insufficient information, the effect of human errors, etc. or due to the effort of quantitative analysis may not be needed or guaranteed. In these occasions, a comparative semi-quantitative or qualitative ranking of risks by experts mastered in the related field might be helpful.

2.4.3.3 Consequence analysis: or Hazards characteristics

The next step in risk assessment in food industry is the hazard characteristics in which the extent and nature of the adverse health effects known to be connected with the unique hazard. This step plus Exposure Assessment is a part of Risk Analysis process of ISO 31000 (2009). If it is feasible, a dose-response connection can be applied between different levels of exposure to the hazards in food at the consumption point and the probability of different adverse health impacts. The needed information can be obtained from animal toxicity studies, clinical human exposure studies and epidemiological data from investigations of illness.

According to the risk goals and objectives designed by risk management, responses could be classified. For instance, for chemical hazards, types of detrimental health effects by various doses of chemical hazards using animal trials, and for microbial hazards, infection, morbidity, hospitalization and death rates relevant to various doses.

The points needed to be considered in hazard properties are as follows:

- Considering current controls to treat the consequences and all correspondent factors that might have an impact on the consequences.
- Relating the risk consequences to the original objectives.
- If it is consistent with the objectives of the assessment, taking into account both prompt consequences and those may appear after a period of time.
- Taking into account the secondary consequences, for example those influence the relevant systems, activities, equipment or organizations.

2.4.3.4 Probability estimation or Exposure assessment:

The exposure evaluation predicts the probability of a subject or people that would be exposed to a hazard. These data could be also associated with the food consumption pattern of the certain consumer population to determine hazard exposure during specific time duration. Origins of information for exposure analysis vary, it could be statistical data and pervious outbreaks from literature or discussing with specialists team familiar with various sides of exposure pathways. The team might consist of food scientist, nutritionist, animal health expert, epidemiologist, risk analyst, and production specialist.
The level of hazards in food change during the food supply chain, therefore, when it is necessary exposure assessment can evaluate changes in levels of hazard during the supply chain process to estimate the probability level at the time of consumption. In food chemical hazards, there might be very little change from levels in production journey (FAO/WHO, 2011). In the microbiological hazards, level of hazards can change due to pathogen growth, and cross-contamination at any step to consumption; and it may add to the complexity of the evaluation. (WHO, 2007)
The following general approaches are commonly employed to estimate probability by ISO 31000 general guidelines for risk management (2009); these approaches may be used individually or jointly:

a) Using historical information to determine events or occasions occurred in the past and be able to estimate their occurrence probability in the future. The information applied should be relevant to the type of system, facility, organization or activity as well as to the operational standards of the involved organization. If according to the history, there would be a remarkably low frequency of occurrence, then any prediction of probability would be uncertain. It would particularly be zero occurrences when one assume the event or circumstance will not occur in the future.

b) Probability predictions using estimating methods for example fault tree analysis and event tree analysis according to Appendix 8.1. When historical information is insufficient or unattainable, it would be required to calculate probability by analysis of the system, activity, equipment or organization and its relevant failure or success levels. In order to provide a prediction of the probability of the top event, numerical data for equipment, humans, organizations and systems from practical experience, or published information sources are then combined. It would be crucial to ensure the due allowance made in the analysis for the possibility of prevalent failure modes including the co-incidental failure of some various parts or components within the system arising from a similar cause. In order to generate probability of equipment and structural failures, simulation methodologies might be necessary to calculate the influences of uncertainties, due to ageing and other degradation processes.

c) Expert opinion can be used in a systematic and structured process to estimate probability. Expert judgements should draw upon all relevant available information including historical, system-specific, organizational-specific, experimental, design, etc. There are a number of formal methods for eliciting expert judgement which provide an aid to the formulation of appropriate questions. The methods available include the Delphi approach, paired comparisons, category rating and absolute probability judgements.

2.4.3.5 Risk evaluation or Risk characteristics

The results of the previous three steps are integrated to generate an estimate of risk, in risk characteristics step. Estimations can be in a number of methods and probability and variability must also be described if possible. A risk characterization often contains narrative on other aspects of the risk assessment, such as comparative rankings with risks from other foods, impacts on risk of various "what if" scenarios, and further scientific work needed to reduce gaps.
Risk characterization for chronic exposure to chemical hazards does not typically include estimates of the likelihood and severity of adverse health effects associated with different levels of exposure. A "notional

zero risk" approach is generally taken and where possible the goal is to limit exposure to levels unlikely to have any adverse effects at all.
In order to determine the level significance and risk type, risk evaluation compares the predicted levels of risk with the risk criteria explained when the context was prepared. To make decisions about prospective actions, risk evaluation benefit from the understanding of risk acquired during risk analysis. Inputs to the decision would include ethical, legal, financial as well as other considerations such as perception of risk.

Decisions may include:

- whether a risk needs treatment;
- priorities for treatment;
- whether an activity should be undertaken;
- which number of paths should be followed;

The criteria used to make decisions are decided during the preparation of context, but it is urgent to be reviewed in more detailed at this stage when specific risks are better known. A single level framework (tolerable risk or threshold) is the simplest for explaining the risk criteria, separating risks that require treatment from the others. The method could consists of following:

a) an upper band (more than threshold) where the level of risk is intolerable; risk treatment is essential whatever its cost;
b) a lower band (less than threshold) where the level of risk is regarded as negligible, or so small that no risk treatment measures are needed.

This classification could be also in three groups of upper band, middle band, and lower band; in which upper band requires risk treatment, middle band requires cost-benefits analysis for the risk treatments, and lower band no need for the further action. The selection of the classification method is mainly depends on experts judgment, kind of industry, budgetary and feasibility of the study.

2.4.4 Selection of techniques

Risk assessment might be applied in various levels of depth and details by implementing one or more number of simple or complicated techniques. The risk criteria produced as a part of preparing the context should be in accordance with the type of assessment and its relevant output. The conceptual relationship among the vast classifications of risk assessment methodologies and the factors available in a certain risk circumstances has been shown in Table 2:8 and Appendix 8.1. It provides explanatory examples of how organizations can choose the convenient risk assessment method in a certain circumstance.

Based on applicable factors, the risk assessment methods should be adopted once the decision has been made and the scope has been defined, as follows: (FAO/WHO, 2011; ISO31000 ISO, 2009)

- The goal of the risk assessment would have a straight impact on the method performed. For instance, if a comparative study among various alternatives is being considered, it might be acceptable to use less detailed consequence models.
- The requirements of decision makers. In some circumstances a high level of details would be necessary in order to make a convenient decision, but in other situations, a more general understanding might be adequate. The decision on the depth to which risk assessment is implemented must reflect the initial understanding of consequences and the level of competence, individual and other resources would be necessary.
- A simple technique that is applied effectively might provide better results in comparison with a more complicated technique that has been inconveniently implemented, as long as it meets the goals and scope of the assessment. Commonly, the effort put into the assessment should be compatible with the potential degree of risk being analyzed as well as the availability of data and information. Some methods would require more data and information, as well as the need for correction or updating of the risk assessment than others. It might be necessary for the assessment to be modified or updated in the future and some methods are more amendable from this perspective considering any regulatory and contractual requirements. Different factors affect the choice of an approach of risk assessment include the availability of resources, the nature of the level of uncertainty in the available information.

Table 2:8 shows the risk assessments tools and techniques, with comparison of their application, and provided data.

Table 2:8: Applicability of tools used for risk assessment (source: ISO 3100 (2009))

Tools and techniques	Risk assessment process				
	Risk Identification	Risk analysis			Risk evaluation
		Consequence	Probability	Level of risk	
Brainstorming	SA[1]	NA[2]	NA	NA	NA
Structured or semi-structured interviews	SA	NA	NA	NA	NA
Delphi	SA	NA	NA	NA	NA
Check-lists	SA	NA	NA	NA	NA
Primary hazard analysis	SA	NA	NA	NA	NA
Hazard and operability studies (HAZOP)	SA	SA	A[3]	A	A
Hazard Analysis and Critical Control Points (HACCP)	SA	SA	NA	NA	SA
Environmental risk assessment	SA	SA	SA	SA	SA
Structure « What if? » (SWIFT)	SA	SA	SA	SA	SA
Scenario analysis	SA	SA	A	A	A
Business impact analysis	A	SA	A	A	A
Root cause analysis	NA	SA	SA	SA	SA
Failure mode effect analysis	SA	SA	SA	SA	SA
Fault tree analysis	A	NA	SA	A	A
Event tree analysis	A	SA	A	A	NA
Cause and consequence analysis	A	SA	SA	A	A
Cause-and-effect analysis	SA	SA	NA	NA	NA
Layer protection analysis (LOPA)	A	SA	A	A	NA
Decision tree	NA	SA	SA	A	A
Human reliability analysis	SA	SA	SA	SA	A
Bow tie analysis	NA	A	SA	SA	A
Reliability centred maintenance	SA	SA	SA	SA	SA
Sneak circuit analysis	A	NA	NA	NA	NA
Markov analysis	A	SA	NA	NA	NA
Monte Carlo simulation	NA	NA	NA	NA	SA
Bayesian statistics and Bayes Nets	NA	SA	NA	NA	SA
FN curves	A	SA	SA	A	SA
Risk indices	A	SA	SA	A	SA
Consequence/probability matrix	SA	SA	SA	SA	A
Cost/benefit analysis	A	SA	A	A	A
Multi-criteria decision analysis (MCDA)	A	SA	A	SA	A

[1] Strongly applicable.

[2] Not applicable.

[3] Applicable.

2.4.5 Risk Assessment tools in food

Risk management in the food supply chain differs from inspection based controls; it must be science based and be developed from a set of food safety objectives. Furthermore, risk management requires a multidisciplinary approach from the management team and integrated risk management through the supply chain will lead to improved business sustainability (Manning & Baines, 2004).

A food safety risk assessment strategy will include:

1. Identifying and ranking the risk inherent in the products and activities in production process.
2. Evaluating the risks in terms of the likelihood of their occurrence and the impact, or severity, if they do occur. This process is often called risk mapping and can be undertaken using a decision tree, graphically or in a matrix.
3. Determining the level of risk the business willing to accept by the ratio of risk and reward.

In the next step, the output of risk assessment provides input data for the risk management process that include:

1. Determining which risks the business is not competent, or willing to manage and either transferring or avoiding those specific risks.
2. Identifying the appropriate risk management techniques and implementing the food safety risk management system required to manage the remaining risks.
3. Monitoring and verifying the effectiveness of the risk management system and developing reporting mechanisms.
4. Implementing the necessary preventative and corrective action to ensure improved performance.

Nestle (2003) determined that we define a safe food as: "one that does not exceed an acceptable level of risk and risk may be assessed by either a science based or value based approach". They argued that "safety is relative; it is not an inherent biological characteristic of a food. A food may be safe for some people and not for others, safe at one level of intake but not at another, or safe at one point in one time, but not later [...]. Decisions about acceptability involve perceptions, opinions, and values, as well as science."

According to Marucheck et al. (2011) Key performance indicators (KPI) can be developed to act as an early warning mechanism to identify when risk is not being sufficiently managed and before food safety incident occurs. This is the approach taken at critical control points (CCPs) when developing a food safety plan and developing measurable target levels and tolerances for control of a food safety hazard as well as a critical limit which separate safe from unsafe food. However, the supporting evidence may not be sufficiently complete to perform a comprehensive risk assessment. This is method is useful specifically where a qualitative rather than quantitative risk assessment is used.

Quantitative science-based risk assessment balances risk against benefit and cost whereas qualitative value-based risk assessment balances risk against threat and outbreaks. Whilst neither method of risk assessment is mutually exclusive, the approach used either individually, or collectively by stakeholders. It will act as a driver in determining how effectively an organisation implements specific strategies such as those addressing food safety management. The stakeholders will, depending on their specific expectations, fit at different points on the quantitative/qualitative risk assessment spectrum.

Risk has been defined in several ways, however the general risk assessment formula which is common in variety of industries and concepts of risks is: (Manning & Soon, 2013)

<u>Risk = Probability * Consequence</u>

Ni, Chen, and Chen (2010) stated that only two input risk variables (severity and probability) are required to construct a risk matrix, and the output risk is only determined by the severity and probability of occurrence.

Food decision makers require tools that enable them to: identify the most significant risks from a public health perspective; reduce risks, by taking into account the feasibility, effectiveness and cost of possible interventions; and allocate efforts and resources accordingly (CAC, 2011).

BS EN ISO 22000:2005 (BSI London, 2005) defined the approaches to hazard and risk assessment and stated that: In many circumstances, the knowledge and expertise of experienced staff using a structured techniques may be sufficient to manage risk. Checklists are quick and easy to use, and can help determine whether design standards and practices are met and whether previously recognized hazards are properly addressed. Where the experience gained by industry has been incorporated into codes and standards, a high level of safety can be achieved by checking for compliance [...] structured review techniques can be used to identify and evaluate previously unforeseen hazards and unintended events that are not adequately addressed by the previous methods. (Manning & Soon, 2013)

The ultimate goal of risk assessment process is to estimate the probability and severity of risk occurrence using qualitative and/or quantitative information and subsequently to identify opportunities for intervention (Schlundt, 2000). However, in order to achieve this, the degree of uncertainty must be recognised and included in any estimates of risk (Davidson, Ryks, & Fazil, 2006). Risk assessment in a food safety context has two meanings. The generic meaning of risk refers to the measurement of risk and the identification of factors that influence it (Schlundt, 2000). The specific meaning of risk assessment is the scientific evaluation of known or potential adverse health effects resulting from human exposure to foodborne hazards (CAC, 2011).

Qualitative risk assessment (Q):

According to Wooldridge and Schaffner (2008), qualitative risk assessment is based on data, while forming an inadequate basis for numerical risk estimations, nonetheless, by using expert knowledge and identification of uncertainties permits risk ranking or into descriptive categories of risk. Hence, qualitative risk assessment can assist a risk manager in priority setting and policy-decision making.

Semi-quantitative risk assessment (SQ):

Semi-quantitative risk assessment forms the bridge between qualitative and fully quantitative methods. Values can be represented with statements and/or numeric scales and some quantitative measures of risk are produced (Davidson et al., 2006).

Quantitative risk assessment (QRA):

According to Voysey and Brown (2000), a QRA should be carried out wherever or whenever possible. However, if no data are available to make such inferences then a quantitative risk assessment is not possible. QRA are usually carried out to evaluate microbiological hazards. A quantitative microbial risk assessment (MRA) produces a mathematical statement that links the probability of exposure to an agent and the probability that the exposure will affect individual (Voysey & Brown, 2000). If a qualitative risk assessment has been done, the risk estimate will be a simple statement that the risk is high/medium/low. If it is a quantitative risk assessment, the risk estimate will be a number, such as predicted illnesses per annum in the population, or the probability of becoming ill from eating a serving of the food.

3 Development of the method

The main objective of this research is to create a model which analyses the various risks involved in a food supply chain and validate the model with the help of case studies on food products companies. This objective is achieved by proposing a new semi-quantitative model in risk assessment, covering the entire food supply chain, from farm to the end consumers. This model (Figure 3:1) is based on two main phases, combination of quantitative and qualitative risk assessment techniques to assess the safety aspects of the food chain, and Key Performance Indicators (KPIs) in different stages (nodes) of the supply chain. This novel approach is applicable in all kind of foods supply chain with no limitation in organization size and operation, while, providing a useful decision making tool for the food supply chain decision makers.

In this model (Figure 3:1) we have two main phases for the food supply chain risk assessment.

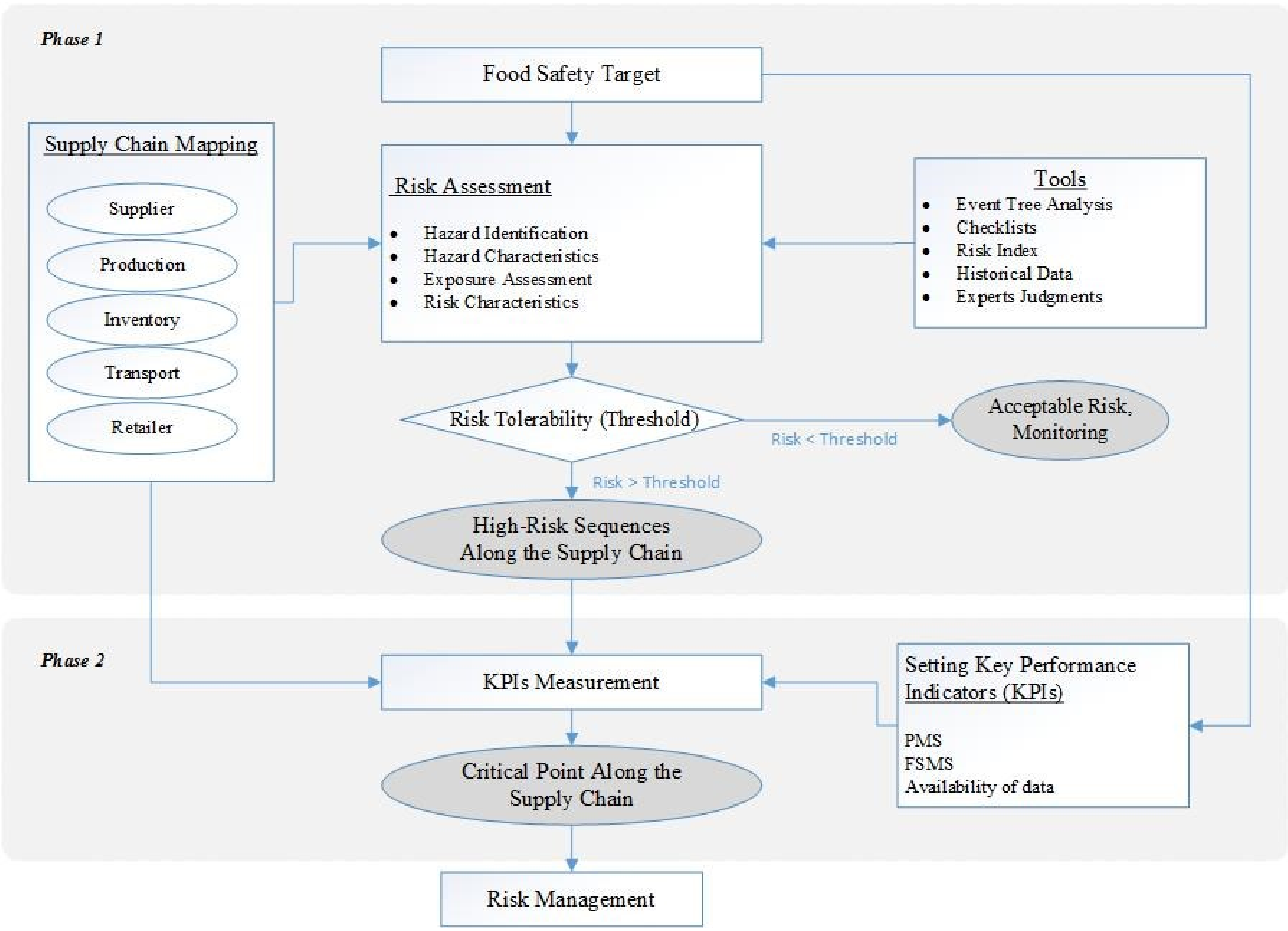

Figure 3:1: Risk Assessment Model in Food Supply Chain Safety Management (Author)

3.1 Phase 1: Risk assessment method

In first step as it is common in risk management procedures, we need to have the definition of food safety and the risk target for our analysis. This definition sets up the objective and aim of the assessments and enables us to recognise the acceptable level of risk. Afterward, the second step is to map the entire Food Supply Chain (FSC) to recognize all the nodes and major players in the network. This step is necessary to have a wider view of the entire operation, as there are many activities and actors involved in the food chain. Furthermore, having the components of a complex system (i.e. FSC) is critically important to analyse the risk in the system. (CAC, 2011)

In third step we need to apply a risk assessment tool (appendix 8.1) relevant to our risk assessment problem and applicable in the food supply chain practice. In this study we used Event Tree Analysis (ETA) due to its advantages and relevance to assess the food safety risk along the FSC based on different consequences and probability of failure in each node.

The definition of ETA and its methodology is described in ISO 31000 (2009) as follow:

ETA is a graphical technique for representing the mutually exclusive sequences of events following an initiating event according to the functioning/not functioning of the various systems designed to mitigate its consequences (Figure 3:2). It can be applied both qualitatively and quantitatively. (ISO31000 ISO, 2009)

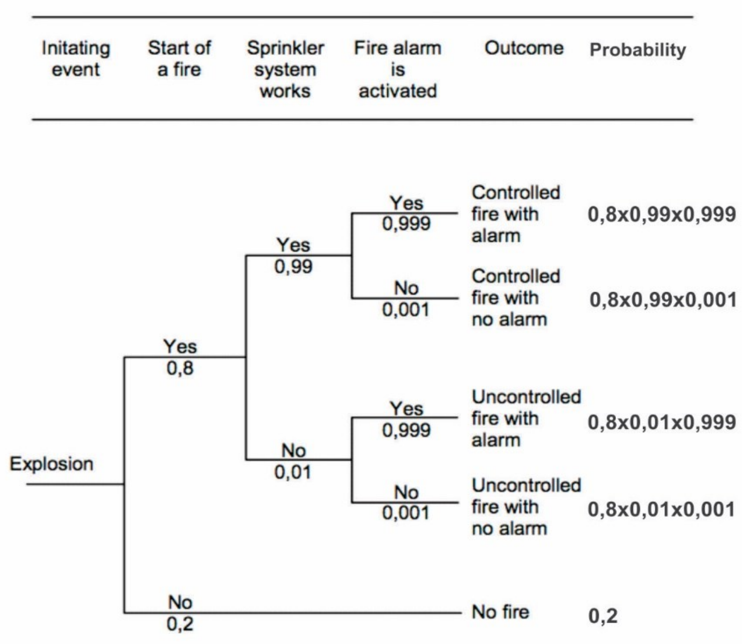

Figure 3:2: Example of ETA (from fire risk analysis)

ETA commonly used for modelling, calculating and ranking of risks based on different failure scenarios following the initiating event. ETA can be used in different stages of the process or life cycle of a product. It could be used qualitatively with the help of brainstorm potential scenarios and sequences of events following a starting event and how outcomes are influenced by various processes, barriers or controls intended to mitigate unwanted outcomes, which makes it more applicable and relevant to the food supply chain practice.

In this study we use ETA in order to analyses different stages of the supply chain in terms of food safety. This stages can be various processes, or controls; and the initial event could be starting the food production event. Using a decision tree demonstrates the pathway (sequence) and any event can be failure along this pathway, with its probability of failure and consequences on the following events.

The input of ETA includes:

- Understanding of the entire processes whereby an initial event starts.
- List of appropriate events
- Information on each events and controls, and their failure probabilities (for quantitative analyses)
- Information on consequence of failure in each event for the following events, and final consequence

The process of ETA starts by an initiating event. This may be starting the production process of a product and then functions or systems which are in place to mitigate outcomes are then listed in sequence. For each function or system, a line is drawn to represent their success or failure. A particular probability of failure can be assigned to each line, with this conditional probability estimated e.g. by expert judgement or historical data. In this way, different pathways from the initiating event are modelled. Each path through the tree represents the probability that all of the events in that path will occur. Therefore, the probability and consequence of each path can be calculated and the outcome risk for each pathway (sequence) can be achieved using (Risk = Probability*Consequence) formula.

Outputs from ETA include the following:

- Qualitative descriptions of potential problems as combinations of events producing various types of problems (range of outcomes) from initiating events;
- Quantitative estimates of event probabilities and relative importance of various failure sequences and contributing events;
- Lists of recommendations for reducing risks; and providing data for the risk management in the following stage.

Advantages of ETA include:

- ETA displays potential scenarios following an initiating event, are analyzed and the influence of the success or failure of mitigating systems or functions in a clear diagrammatic way;
- It accounts for timing, dependence and domino effects that are cumbersome to other models;
- It graphically represent sequences of events which are not possible to represent when using fault trees.

Limitations of ETA include:

- In order to use ETA as part of a comprehensive assessment, all potential initiating events need to be identified. This may be done by using another analysis method (e.g. HAZOP, PHA), however, in our model we overcome this limitation by using Supply Chain Mapping process (it is more illustrated in the case studies in Chapter 4 and 5).

- With event trees, only success and failure states of a system are dealt with, and it is difficult to incorporate delayed success or recovery events. As the objective of this phase of study is identifying the high risk sequence of events of the FSC, fulfill our requirements in first phase.

- Any path is conditional on the events that occurred at previous branch points along the path. Many dependencies along the possible paths are therefore addressed. However, some dependencies, such as common components, utility systems and operators, may be overlooked if not handled carefully. To overcome this limitation, in this study we use combination of the ETA and KPIs to cover all aspects of the food supply chain and avoid overlooking any components of the system (illustrated in phase 2).

3.1.1 Probability and Consequence Estimation

In this study we use ETA which has strong visualize advantage in combination with using the check list, historical data in food outbreaks, and expertise knowledge to cover both known and possible unknown issues in food safety. Using this method enables us to estimate the probability of failure in each event and the consequence of each pathway to calculate to total risk.

Check-lists are lists of hazards, risks or control failures that have been developed usually from experience, either as a result of a previous risk assessment or as a result of past failures based on ISO 31000 (2009).

A check list is commonly used to identify hazards and risks or to assess the control points. They could be used at any step of the life cycle of a product, system or process. They could be used in combination of other risk assessment tools but are most useful when applied to check all aspects have been covered after an imaginative technique.

The input of the check lists are prior data and experience on the issue, and the procedure is as follow:

- The scope of the activity is defined;
- A check-list is selected which adequately covers the scope.
- Check-lists need to be carefully selected for the purpose.
- The person or team using the check-list steps through each element of the process or system and reviews whether items on the check-list are present.

3.1.1.1 Semi-quantitative index

In order to assign the probability and severity to the ETA the risk assessor team analyzed the probability and severity of each consequence using the following semi-quantitative method.

Severity of each undesired outcome is defined using the following Index table:

Table 3:1: Severity Index (Expert judgment)

Number	Level	Description
1	Minor	Minor health issue without medication
2	Moderate	Less serious health issue, medication
3	Major	Serious health issue, hospitalization
4	Catastrophic	Critical health issue, risk of death

And the probability of each failure using the following Index Table 3:2.

Table 3:2: Probability Index (taken from (WHO, 2008), Figure 4:2)

Number	Level	Description
1	Rare	Source of contamination, but likely to be eliminated by subsequent process
2	Infrequent	Potential contributory factor
3	Common	Contributory factor
4	Probable	Principle contributory factor

The probability and severity of safety failure in each part of the food chain is achieved using historical data (food outbreaks), check-lists of food producers, plus expertise opinion of food safety team (risk management, food biologist, chemist experts). The probability is obtained by devoting index number 1 to 4 for each hazard credible in each step of the process. The indexes are then sum up to obtain for example each step of the process a cumulative index of probability that has been translated in a probability range through the use of military index. Afterward, calculating the total index (Cumulative Index of Failure) for probability of failure in each node of the supply chain, following by using the military index Table 3:3.

Table 3:3: Quantitative military index for probability of failure (WHO 2009)

Category	Cumulative Index of Failure	Probability range	Average of probability range
1	=<4	< 10-5	<0.00001
2	4<=8	10-3 to 10-4	0.0005
3	8<=12	10-2 to 10-3	0.005
4	12<=16	10-1 to 10-2	0.05
5	16<=20	>10-1	>0.1

Because we have minimum 1 failure and maximum 5 failure in each node, the probability index varies between 1 *1(rare) to 5*4 (probable), thus the probability index is between 1 -20.

3.1.2 Risk Tolerability (Threshold)

The concept of risk tolerability or acceptable level of risk is very important issue in risk assessment. Regarding the food safety and public health, there are levels of risks that are so great that must not occur at all costs, on the other hand there are other risk levels that are so low and do not worth to invest the resources to reduce them (Whipple, 1987). Therefore, the characteristics of hazards, public health, budgetary, technical feasibility of risk mitigation and food safety target are associated with determining the risk tolerability or acceptable risk level. Considering that society could not prevent or eliminate all health impacts with food exposure issues. Thus, acceptable risk level represents the tolerable limits to danger that the society or company is prepared to accept in consequence of potential food outbreak. In this study, we need to set the risk tolerability in order to identify which ETA pathway has higher than threshold risk for further action to reduce or mitigate the risk.

The threshold in this study is calculated using Risk Matrix.

Table 3:4 Risk Matrix

Severity \ Probability	1 (0.00001)	2 (0.0005)	3 (0.005)	4 (0.05)	5 (0.1)
Minor(1)	Low 0.00001	Medium 0.0005	High 0.005	High 0.05	High 0.1
Moderate(2)	Low 0.00002	Medium 0.001	High 0.01	High 0.1	High 0.2
Major(3)	Medium 0.00003	Medium 0.0015	High 0.015	High 0.15	High 0.3
Catastrophic(4)	Medium 0.00004	High 0.002	High 0.02	High 0.2	High 0.4

In the risk matrix, there are severity column and probability row. The green cells show events with Low Risk, that means event with probability of 1 or 2 and minor severity. These events have acceptable level of risk, therefore there is no need to intervene and reduce the risk.

The yellow cells represent Medium Risk, and red cells show the High Risk events. Generally in the yellow cells (or medium risk) of risk matrix, the risk reduction policy depends on its costs and benefits analysis by the companies; however, in red cells (or high risk) the risk should be reduced to acceptable level without considering its costs. In this study, any sequence (pathway) in the ETA that has Risk in Yellow or Red cells we consider as high-risk sequence that requires further action.

3.2 Phase 2: KPIs measurement

As mentioned in the phase 1, ETA provides different pathways (sequences) based on different probability and consequence of success/failure in each event. We can identify the risk for each pathway and recognise the risk that are above our risk limit (threshold). However, each pathway may consist of more than one failure event, and also each event could involves more than one node of Food Supply Chain (e.g. supplier, production, etc.). Thus, it is required to identify which node has the lowest safety to intervene and reduce or eliminate the risk. The lowest safety node, has been identified through the adoption of KPIs (key performance indicators), describing such an impact.

In this phase, based on the Performance Measurement literature (Aramyan et al., 2007; Beamon, 1999; Gunasekaran & Kobu, 2007; Gunasekaran et al., 2004); and safety expertise judgment, we selected appropriate KPIs for each activities of the supply chain that match our safety target as well.

These KPIs (Table 3:5) are aiming to analysis the safety of foods in different activities that include five main steps of Supplier, Production, Transportation, Inventory (or storage), and Retailer. However, each node of the supply chain could covers one or more activities (or group of KPIs), and not necessarily all the KPIs groups. That is more illustrated in the case company results (section 4.2). Another important factor in defining KPIs is considering the human factors as an indicator whenever the process involves human interaction according to our supply chain map.

The KPIs have been measured in case study 1 & 2 using questionnaire in appendix section (8.2).

Table 3:5: semi-quantitative Supply Chain KPI

Supplier	KPI	Definition
S1	Product selection based on regulation or standards	This indicator measures the percentage of those products that are Listed on standards , or other approved product list, or standard treatment guidelines
S2	Percentage of Products that Undergo Quality Testing	This indicator measures the percentage of purchased individual products that undergo Quality testing
S3	Traceability	Information availability, use of barcodes, standardization of quality systems
S4	Order Compliance For each supplier	This indicator measures the percentage of orders that meet the set criteria (e.g., correct products received in the correct amounts)
S5	Human Factor	Competence of personnel in the food safety (HACCP, GMP, GAP)

Production	Indicator	Definition
P1	Percentage of Products that Undergo Quality Testing	This indicator measures the percentage of individual products/lots/shipments that undergo Quality testing
P2	Maintenance	Corrective maintenance to preventive maintenance ratio
P3	Traceability	Information availability, use of barcodes, standardization of quality systems
P4	Working conditions	Standard conditions that ensure a hygienic, safe working environment, with correct handling and good conditions
P5	Human Factor	Competence of personnel in the food safety (HACCP, GMP, GAP)
Inventory	**Indicator**	**Definition**
I1	Adequate Shelf Life	This measures the percentage of products received in a shipment with the pre-defined amount of shelf life
I2	Quality of products in the warehouse	The percentage of stock for a product that is in good quality and usable (not expiration or damage)
I3	Traceability	Information availability, use of barcodes, standardization of quality systems
I4	Storage conditions	Standard conditions required for storage of the products that are optimal for good quality
I5	Human Factor	Competence of personnel in the food safety (HACCP, GMP, GAP)
Transport	**Indicator**	**Definition**
T1	On-Time Arrivals To destination	This indicator measures the percentage of shipments arriving on time
T2	Percentage of Shipments Arriving in Good Condition	This indicator measures the percentage of shipments arriving in good condition without damage to the products
T3	Traceability	Information availability, use of barcodes, standardization of quality systems
T4	Storage and transport conditions	Standard conditions required for transportation and storage of the products that are optimal for good quality
T5	Human Factor	Competence of personnel in the food safety (HACCP, GMP, GAP)
Retailer	**Indicator**	**Definition**

R1	Customer satisfaction	Registered complaints from customers about product quality or safety
R2	Maintenance	Corrective maintenance to preventive maintenance ratio
R3	Traceability	Information availability, use of barcodes, standardization of quality systems
R4	Working conditions	Standard conditions required for storage and selling the products that are optimal for good quality
R5	Human Factor	Competence of personnel in the food safety (HACCP, GMP, GAP)

The method to analyse the total KPIs in each node, is using quantitative index (Table 3:6)

For each nodes of the supply chain the relevant KPIs need to be scales according to the following table:

Table 3:6: KPI measurement Index

KPI Scale	Definition	Quantitative Index
A	Very High	50
B	High	20
C	Medium	0
D	Low	-20
E	Neglectable	-50

And assigning weight (Table 3:7) for each KPI, in order to know which KPI has more importance regarding the level of food safety.

Table 3:7: Weight Index for each KPI

Weight Index	Scale
4	Critical
3	Important
2	Moderate
1	Low

Afterward based on the following method we could measure the total KPIs index for each node.

Equation 1: Total KPIs index

For each KPI element (KPI) % * (Weight Index) = KPI Indicator

For each supply chain node Σ KPI Indicator

Then we need to use the same approach for different supply chain nodes (supplier, production, transport, storage, and retailer), where it is applicable. Table 3:8

Table 3:8: Total KPI measurement for each node

KPI elements for each node	Weight Index	KPI Index
1	...	...
2	...	...
…	...	...
…	...	...
Total KPI for each node		Σ KPI

Comparing the Σ KPI Indicator in each node of the high-risk pathways, enables us to recognize the weakest point in terms of safety along the food supply chain (the node with lowest Σ KPIs, has the lowest food safety). Afterward, we are able to reduce or mitigate the risk in the next stage of the risk management process and also to assess the effectiveness of the measures.

4 Case Study 1: Dairy Production

The first case study in this research is an SME dairy production in north Italy (for the purpose of confidentiality, we call it company A). The main products of the company A include milk, yogurt, cheese and ice-cream. All the products made from pasteurized milk, and the entire process of the dairy supply chain (excluding transportation and retailers) is operating by the company. Cattle feeding production including (farming, harvesting), keeping and feeding cattle, milking process and production of all products are performed inside the company's boundary. The number of stuff working in the company A is about 12-14 persons. With regards to the food safety, the company applied Codex Alimentarius[4], and HACCP and performs safety procedure based on these regulations. The food pathogen analysis performs internally by the food biologist and externally through food laboratory, in different time schedule depends on products types.

[4] The Codex Alimentarius Commission was created in 1963 by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme.

The interview performed with food biologist who is also involved in operating of HACCP, with collaboration of risk assessor and supply chain specialist. In the first step the entire dairy supply chain has been viewed by the team, and has been mapped in details and complete process. The information about Critical Control Point (CCP) and Control Point (CP), as well as control measures has been obtained via HACCP document and observation by research team in the company. Other important control points and control system (e.g. alarm system) are also mentioned in the supply chain map for further analysis.

In the second step the KPIs questionnaire have been answered by the interviewee, to identify the weakest point of each supply chain node in terms of food safety. And the third step was to identify the probability and consequence of safety failure in each supply chain node, using the ETA analysis. The ETA analysis designed and performed with a team of food biologist, risk management specialist, and chemist professors, as well as food safety expert in the company. The consequence of each failure in ETA analysis have been identified using team experts opinions, and the probability has been recognized using food outbreak statistics, data from last events, check-lists and comparing to the current situation of the company A.

In order to have better view point of the dairy safety issues and outbreaks a comprehensive literature review has been performed that is defined in section 4.1.

4.1 Background of the safety management in dairy production

Milk and its diverse products are crucial sections of the food supply chain, as they are an excellent nutrients source for humans. Besides, dairy products are also known as added-value products (e.g. Calcium-enriched, lactose-free, added pro- biotics, omega-3) amongst functional foods and account for 43% of a $16 billion market (Özer & Kirmaci, 2010).

The diversity of dairy products is large: it could include liquid milk, concentrated milk, milk powder, butter, cream, ice cream, fermented dairy products (e.g. cheese, yogurt), dairy beverages, etc. Dairy products can be consumed without further processing, as well as utilized in the food production industry (e.g. milk powder). The overall worldwide annual production of milk is about 695 million tons that counts to 117 billion EU annual sales. Cow's milk represents 84% of the total milk production (IDF, (2009)) which most of it will be sold as a heat-treated product (e.g. pasteurized) or converted to dairy products (e.g. cheese, yogurts, milk powder). More notably, milk and milk products are readily consumed by almost all population groups (e.g. infants, children, teenagers, middle-aged and the elderly). (Arvanitoyannis, 2009)

Dairy products accounted for more food-borne-illness hospitalizations than 16 other commodity foods over an 11-year period Table 4:1, based on a new study from the Centers for Disease Control and Prevention (CDC). Dairy products ranked second, resulting in 1.3 million illnesses and 10% of food-borne-illness deaths from 1998 through 2008. Dairy products accounted for 16% hospitalizations, followed by leafy vegetables, 14%, poultry, fruits and nuts. (Painter et al., 2013)

Table 4:1: Sources of food- borne illnesses acquired in the United States 1998-2008 (Painter et al., 2013)

	Illness		**Hospitalization**		**Death**	
1	Leafy	22.3	Dairy	16.2	Undetermined	25.2
2	Dairy	13.8	Leafy	13.5	Poultry	19.1
3	Fruits-nuts	11.7	Poultry	11.5	Dairy	9.7
4	Poultry	9.8	Vines	10.5	Vines	7.0
5	Vines	7.9	Fruits-nuts	10.1	Fruits-nuts	6.4
6	Beef	6.6	Undetermined	8.1	Leafy	6.0
7	Eggs	6.0	Eggs	7.1	Pork	5.7
8	Pork	5.4	Beef	5.4	Fish	4.9
9	Grains-beans	4.5	Pork	5.1	Eggs	4.9
10	Roots	3.6	Fish	2.9	Beef	3.8
11	Mollusk	3.0	Roots	2.6	Sprouts	1.9
12	Fish	2.7	Grains-beans	2.5	Grains-beans	1.9
13	Undetermined	1.1	Mollusk	2.5	Roots	1.4
14	Oils-sugars	0.7	Sprouts	1.2	Mollusk	1.4
15	Crustacean	0.5	Oils-sugars	0.3	Game	0.2
16	Sprouts	0.3	Crustacean	0.2	Oils-sugars	0.2
17	Game	0.1	Game	0.2	Crustacean	0.2
18	Fungi	0.1	Fungi	0.1	Fungi	0.1

During 2015, 59 notices regarding milk and milk products have been reported by the EU Rapid Alert System for Food and Feed (EU Rapid Alert System, 2015). Most of the reports alarmed the presence of pathogenic microorganisms in dairy products (e.g. Escherichia coli O157:H7, Staphylococcus, Salmonella, Listeria monocytogenes,), spoilage micro-organisms (e.g. molds) and hygiene indicator micro-organisms (e.g. coliforms), while a recent announcement observed the presence of antibiotics in milk. It is apparent, from these statistics and reports that milk and milk products are available throughout the world and possible microbiological, chemical or physical contamination would impact on a vast population.

With respects to the dairy products the new Directives EC No.852/2004 and 853/2004 have replaced the Dairy Hygiene Directive 92/46/EEC, and regulations 1774/2002 and 79/2005 (dairy firms disposing milk and dairy products) and Regulation 18d3/2005 (dairy products intended to be used as animal feed) (Komorowski, 2006).

However, the FVO (2008) report has recognized limitations in the quality control and safety of the raw milk in countries such as Hungary, Spain, and Poland while some progress was noticed in Cyprus, Belgium, Greece, and Denmark. Furthermore, the same report mentioned that compliance with community requirements concerning to remains and veterinary medicines controls in foods of animal origin in Greece, Romania, Portugal and Bulgaria suffered from significant weaknesses. These facts prove the need for rigid adherence to hygiene regulations (Food Safety Management Systems) by the producers, frequent audits by the proficient local authorities as the safety and quality of milk and milk end-products is of vital importance.

4.1.1 Risk management and standards in the dairy industry

Different levels of authorization bodies and international agencies are relying increasingly on risk assessments methods for decision-making process in public health, international trade, and efficient resource allocation in food industry (FOODS, 2005). In this regard, numbers of authors have notified the need for the application of risk assessment techniques in food safety management. (Voysey & Brown, 2000; Wooldridge & Schaffner, 2008)

In order to apply risk assessment methods, scientific data is needed regarding the nature, frequency and influence of food safety hazards on public health. Therefore, the severity of a foodborne illness should be combined with its occurrence in humans to precisely describe risk. (FAO/WHO, 2011)

The most common risk assessment and standard tool in the dairy industry is HACCP principle. Several research have been concerning the application of HACCP in dairy industry for different kind of products such as pasteurized, and condensed milk (Ali & Fischer, 2002), variety of cheeses (Arvanitoyannis, 2009), yogurt (Sandrou & Arvanitoyannis, 2000), ice cream (Arvanitoyannis, 2009).

However, the application of HACCP on dairy farms means nothing more than structuring and formalizing what the truly good farmer would be doing anyway (Ryan, Wall, Adak, Evans, & Cowden, 1997). Therefore, the HACCP does not necessarily make food safe, but its appropriate implementation improve the food safety, and it should not be used as a tool for governments or politicians to increase the confidence of consumers (Motarjemi & Mortimore, 2005). The microbiological conditions for pasteurized dairy products, are explained in the EU Directive 1441⁄2007 (Directive, 2007), all the safety and quality criteria for milk and milk products e.g. animal hygiene, hygiene in farm, temperature control, and microbiological quality of milk, labeling and packaging of dairy products. These directives are required in identification of CCP's and control limits.

Most of the identified hazards are microbiological, thus temperature treatments (e.g. pasteurization) and temperature control (cooling, freezing) are critical for the safety of the end product microbiologically. The chemical and physical hazards in dairy products are equally important to microbiological hazards, although much less frequent. Chemical hazards such as veterinary residues, Aflatoxin M1 are very important but their frequency is much lower (EU Rapid Alert System 2015). According to Arvanitoyannis (2009) physical hazards in dairy products are mainly related to packaging, labelling and contaminations with foreign objects, and are also low in numbers. Physical hazards can be detected by X-ray that identifies foreign bodies such as metal, stone, or glass in sealed packages.

4.1.2 Outbreak of food pathogen in dairy products

Contamination of dairy products with microbiological hazards can occur from different sources involving intrinsic contamination from infected cattle, or extrinsic contamination stem from environmental contamination either from the animal at the milking process, or indirectly from farm environment or the equipment (Sakkas, Moutafi, Moschopoulou, & Moatsou, 2014). Jorritsma and Hofste (2011) identified less hygienic on-farm practices was the source of salmonella antibodies in bulk tank milk in the Netherlands. Moreover, the surface of equipment in milking or cooling could be a critical source of milk contamination. Therefore, hygiene and maintenance of the equipment which are in contact with milk is significant for tanks, liners, milk tubes, and gaskets.

The bulk milk tanks for storage of raw milk on the farm is one of the important points in dairy safety and control of temperature is critical in this point. Often farm tanks have stainless steel surfaces that are easier to clean but other parts of the tank (e.g. valves, gaskets) and milking machines have been associated with contamination problems (Castle & Watson, 1985). Hygiene and cleaning of the tank equipment's could be a three-stage process: cold water rinse, cold or warm water spray with purifier and a following cold water rinse. Potential parts for contamination are valves and outlet ports that may act as sites for the build-up of bacteria. (Castle & Watson, 1985)

Pasteurization is considered to destroy all common bacterial pathogens in raw milk. Broad field studies on the survival of Salmonella spp., E. coli O157:H7, and L. monocytogenes in pasteurized milk exposed varying capabilities of these pathogens to survive in a temperature of 60–74 °C after minimum thermal exposure of 16s (Farber, 1989). However, the sufficient pasteurization of milk is obtained by heating at 63°C for 30 minutes, or at 72°C for 15 seconds at minimum. These actions are adequate to destroy the most heat-resistant of the non-spore forming pathogenic organisms (Akineden, Hassan, Schneider, & Usleber, 2008). Many of the contributing factors in dairy outbreaks were connected to the use of raw unpasteurized milk, faulty pasteurization equipment or process, or post-pasteurization contamination that is a risk factor of human foodborne disease.

In the cheese products, the most important contributing factor in outbreaks stem from animals or the environment (62%, Table 4:2: Contributing Factors Reported in foodborne disease outbreaks associated with cheese, 1998-2011 by CDC) in unpasteurized milk, while this factor was not reported in cheese made from pasteurized milk. The main contribution factor in pasteurized milk is related to worker health and hygiene (35%) or handling by an infected person (31%). Campylobacter infection was reported to be connected to cheese curds by dairy production that had repeated issues resulting in inadequate pasteurization. Listeria was reported in two outbreaks, and the most contributing factor to outbreaks stem from deficiencies in hygiene and worker health, consistent with the large quantity of outbreaks affected by norovirus. Norovirus outbreaks are often connected to cheese trays or other kinds of cheese commonly found in restaurants. (Hannah & BehraveshCasey, 2014)

Table 4:2: Contributing Factors Reported in foodborne disease outbreaks associated with cheese, 1998-2011 by CDC (Hannah & BehraveshCasey, 2014)

Contributing factor description	Milk used to make cheese	
	Unpasteurized (n=26) n (%)	Pasteurized. (n=26) n (%)
Raw product/ingredient contaminated by pathogens from animal or environment	16(62)	2(8)
Ingestion of contaminated raw products	11(42)	1(4)
Insufficient lime and/or temperature during cocking/heat processing or reheating	10(38)	1(4)
Inadequate processing (acidification, water activity, fermentation)	2(8)	0(0)

Contributing factor description	Milk used to make cheese	
	Unpasteurized (n=26) n (%)	Pasteurized. (n=26) n (%)
Allowing foods to remain at room or warm outdoor temperature, for several hours preparing foods a half day or more before serving	2(8)	1(4)
Cross-contamination from raw ingredient of animal origin	1(4)	4(15)
Inadequate cleaning of processing/preparation equipment/utensil	1(4)	5(19)
Improper cooling or cold-holding	1(4)	5(19)
Bare-handed contact by handler/worker/preparer	0(0)	9(35)
Handling by an infected person or carrier of pathogen	0(0)	8(31)
Storage in contaminated environment	0(0)	6(23)
Glove-handed contact by handler worker/preparer	0(0)	5(19)

Table 4:3 shows the summary statistics of dairy product outbreaks in different countries, their source of pathogens, the consequences, and kind of contaminated dairy products.

Table 4:3: Foodborne disease outbreaks involving dairy products (Denny, Buttriss, & Finglas, 2009; Kousta, Mataragas, Skandamis, & Drosinos, 2010; Oliver, Boor, Murphy, & Murinda, 2009)

Year of Outbreak	Country	No. of cases	Source of Pathogen	Type of food
1983-4	Switzerland	122	L monocytogenes	Vacherin Mont d' Or (unpasteurized)
1984	Canada	2700	Salmonella typhimurium	Cheddar cheese (contaminated)
1984-5	Scotland	>13	Staphylococcus aureus	Sheep's milk cheese (unpasteurized)
1985	Switzerland	>40	Salmonella typhimurium	Vacherin Mont d' Or (unpasteurized)
1985	US	>142	L monocytogenes	Mexican style cheese (raw milk mixed with pasteurized)
1988-89	English	155	Unknown	Stilton cheese (unpasteurized)
1989	England	42	Salmonella dublin	Irish soft cheese (unpasteurized)
1989	US	164	Salmonella spp	Mozzarella

Year of Outbreak	Country	No. of cases	Source of Pathogen	Type of food
1992	England	10	Salmonella livingstone	Cheese
1993	France	273	Salmonella paratyphi	Goats' milk cheese (unpasteurized)
1994	Scotland	>20	E. coli O157 :H7	Farm –produced cheese (unpasteurized)
1995	France	20	L. monocytogenes	Brie de Meaux (unpasteurized)
1995	Malta	135	Brucella melitensis	Soft cheese (unpasteurized)
1995	Switzerland	>25	Salmonella Dublin	Cheese
1996	England, Scotland	>84	Salmonella spp.	Cheddar Cheese (pasteurization failure)
1996	Italy	8	Clostridium botulinum	Mascarpone
1997	California, US	31	Salmonella typhimurium	Mexican style
1997	California, US	147	Salmonella typhimurium	Cheese (unpasteurized)
1998	Florida, US	25	Salmonella spp	Cheese
1998	Oregon, US	8	Salmonella typhimurium	Homemade cheese
2000	Pennsylvania, US	9	Salmonella enteritidis	Ice cream
2000	N. Carolina, US	12	L. monocytogenes	Queso fresco
2000	Michigan, US	18	Campylobacter jejuni	Homemade cheese (unpasteurized)
2000	Florida, US	6	Norovirus	Mozzarella
2001	Connecticut, US	4	Salmonella Newport	mozzarella
2002	Indiana, US	25	Norovirus	Cheese
2003	California, US	11	Campylobacter spp.	Queso fresco
2003	Connecticut, US	26	Norovirus	Ice cream
2004	Washington, US	14	Norovirus	Cheese
2004	Arizona, US	18	Norovirus	Ice cream
2005	California, US	23	Clostridium perfringens	Ice cream

Year of Outbreak	Country	No. of cases	Source of Pathogen	Type of food
2005	California, US	12	Salmonella spp.	Queso fresco
2006	Washington, US	58	Campylobacter jejuni	Homemade cheese (unpasteurized)
2006	Kansas, US	5	Bacillus ssp.	Chevre
2006	Connecticut, US	11	Norovirus	Swiss-type cheese

Table 4:4 demonstrates the summary report on trends and sources of main agents in food-borne outbreaks in EU (2013); performed by European Food Safety Authority (EFSA). The probabilities and consequences of food-borne outbreaks in terms of number and percentage of hospitalized and deaths are also provided

. Table 4:4: Main foodborne disease outbreaks in the EU (2013), their source and severity (EFS, 2015)

Causative agent	Strong-evidence outbreaks					Weak-evidence outbreaks					Total outbreaks	Total %
	N	%	Cases	Hospitalised	Deaths	N	%	Cases	Hospitalised	Deaths		
Salmonella	315	37.54	4371	1134	3	853	19.58	4338	1033	2	1168	22.48
Viruses	87	10.37	2023	126	0	855	19.62	7568	1841	0	942	18.13
Bacterial toxins	208	24.79	4006	163	1	626	14.37	5197	289	0	834	16.05
Campylobacter	32	3.81	478	15	0	382	8.77	1314	131	0	414	7.97
Other causative agents	76	9.06	520	46	1	56	1.29	445	27	0	132	2.54
Other bacterial agents	14	1.67	213	25	3	66	1.51	688	84	0	80	1.54
Escherichia coli, pathogenic - Verotoxigenic *E. coli* (VTEC)	12	1.43	154	36	0	62	1.42	353	70	0	74	1.42
Parasites	24	2.86	243	128	0	17	0.39	67	6	0	41	0.79
Yersinia	1	0.12	2	0	0	7	0.16	14	2	0	8	0.15
Escherichia coli, pathogenic (excluding VTEC)	1	0.12	128	0	0	0	0	0	0	0	1	0.02
Unknown	69	8.22	1386	138	1	1433	32.89	8454	652	0	1502	28.91
Total	839	100	13524	1811	9	4357	100	28438	4135	2	5196	100

As it is shown on the table Salmonella shows to have high probability of daises hazards (37.5 %). Following by Bacteria Toxins (24.8 %) and Virus (10.3 %), while Salmonella has the highest severity of consequence (3 death) among other pathogens. Viruses and bacterial toxins have high number of hospitalized (126 and 163) but low number of fatal (0 and 1) respectively.

In the same report performed by European Food Safety Authority (EFS, 2015), Figure 4:1 compares the Distribution of all food borne outbreaks per casusative agent in the EU, 2008-2013. Main agents in food-outbreaks in EU during 2008 to 2013 and number of outbreaks are illustrated. Based this diagram Salmonella and Virus have been the first two main source of known outbreaks during these years (excluding unknown agents), while, Yersinia and Parasites have had the lowest number of outbreaks between 2008 to 2013.

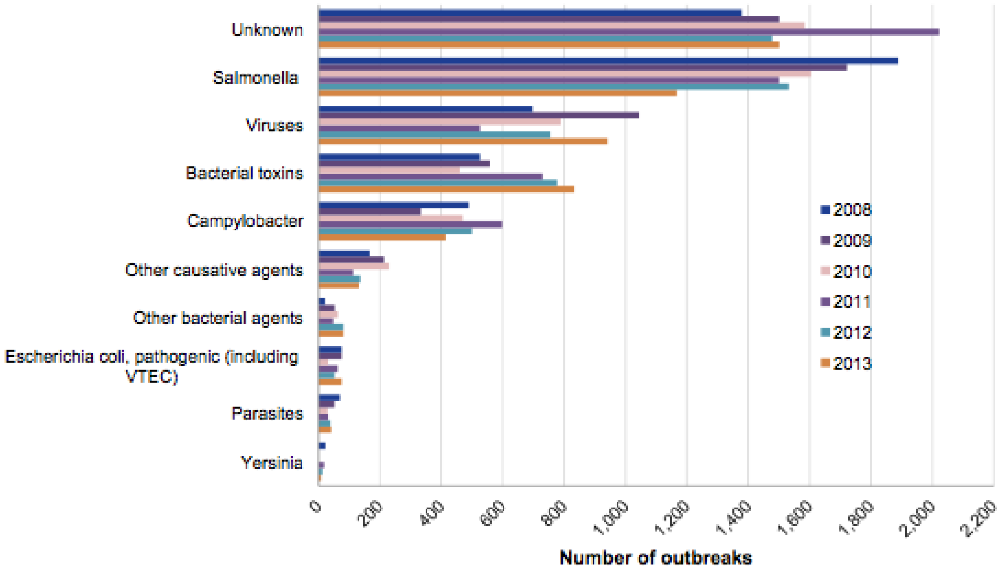

Figure 4:1: Distribution of all food borne outbreaks per casusative agent in the EU, 2008-2013(EFS, 2015)

4.1.3 Probability and severity of failure in dairy supply chain

In the Figure 4:2 the summary of the most significant food pathogens within dairy products is collected according to the food born outbreak statistics and literature. As this figure presents, the dairy products are grouped into Milk, Cheese, and Ice-cream/ yogurt. In each product group, the main contribution of the pathogens and their likelihood of occurrence within the supply chain (pre-processing, processing, and post-processing) is displayed and categorized. Using the data in the following table could facilitate the estimation of the food born probability in each nodes of the dairy supply chain, with consideration of the specific characteristics' of our case study, these probability could alter using expertise judgments.

■	Principal contributory factor
▲	Contributory factor
●	Potential contributory factor
—	Source of contamination, but likely to be destroyed during subsequent processing
M	Multiplication during process
T	Toxin survives hear process
C	Contamination
S	Survival
G	Growth

Food product (vehicle)	Process	Etiologic agent of concern or microbe that produce it	Raw product/ingredient pre-processing								Processing or preparation (contamination, survival, proliferation) in food processing plant.														Post-processing/ storage/ transport					
			Colonized infected animal (C)	Animal feces manure (C)	Animal access to human sewage (C)	Soil contamination (C)	Contamination by worker (C)	Inadequate cooling (G)	Food contaminated (C)	Water contaminated(C)	Improper pH adjustment (S/G)	Improper n adjustment (salt conc.) (G)	Cross contamination(C)	Contamination by food worker (C	Improper cleaning of equipment(C)	Environmental contamination	Organism/toxin survives process (S)	Heat process failure(S)	Manipulation/spread during process (G	Room-outdoor-temperature holding (G	Improper cooling(G)	Inadequate refrigeration(C)	Contamination during cooling (C	Improper or defective packaging (C/G	Contamination during reconstitution (C)	Contamination by person (C)	Improper cleaning of equipment (C)	Improper cooling (G)	Inadequate refrigeration (G)	Room-temperature holding(G)
Milk	Row	Salmonella	■	■			●	■	■	●					●					▲	■	▲				●			■	
		Campylobacter jejuni	■	■				●							●					▲	■	▲							■	
		Yersinia enterocolitica	■	■				■		●										●	■	▲							■	
		Staphylococcus aureus	■				■	■						●	●					■	■	▲				●			■	
		Streptococcus pyogenes	■				■	■						●	●					■	■	▲				●			■	
		Escherichia coli	■	■			●	■	●	●					●					▲	■	▲				●			■	
		Brucella	■					■												●	■	▲							■	
		Listeria monocytogenes	■	■		■		●							●					●	■	▲							■	■

	Cooked pasteurized, or Heat processed	Salmonella	—	—			—	—	—	—			▲	●	▲			■	●	■	■	■	●			●			■	■
		Escherichia coil	—	—			—	—	—	—			▲	●	▲			■	●	■	■	■	●			●			■	■
		Yersinia enterocolitica	—	—				—		—			●		▲			■	●	■	■	■	●						■	■
		Staphylococcus aureus					—	—					●	▲	▲		T	■	●	■	■	■	●			●			■	■
		Listeria monocytogenes	—	—		—		—					▲		▲	●		■	●	■	■	■	●			●			■	■
	Dried	Salmonella	■	■			●	■	■	●			▲		●	●	■		●					●	●		●			
		Yersinia enterocolitica	■	■				■		●			●		●	●	■		●					●		●				
		Staphylococcus aureus	■				■	■						■	●		T		●					●	●					
Cheese	Fermented	Salmonella	■	■				■	■	●	●	●		●			■									●				
		Staphylococcus aureus	■				■	■			●	●		■			T		M			●				●				
		Clostridium botulinum	■	▲		■					●	●					■													
		Brucella	■					■			●	●					■													
		Escherichia coli	■	■			●	■	●	●	●	●		●			■													
		Listeria monocytogenes	■	■		■		■			●	●				●	■													
		Histamine									●	●					■		M											
Yogurt Ice-cream	Whipped Frozen	Staphylococcus aureus	■				■	■						■			■			■	■	■				●				●
		Salmonella	■	■			●	■	■	●				●			■				▲									
		Staphylococcus aureus	■				■	■						■			T				▲					●				
		Salmonella typhi			▲		■	■						■			■				●					●				

Figure 4:2. Probability and severity of failure in dairy supply chain source (WHO, 2008)

4.2 Applying the method

In this section we apply the developed method (section 3) in the case company A, and analyze the applicability of the method in practice.

4.2.1 Supply chain mapping

Dairy chains link the actors and activities involved in production of milk and milk products to the final consumer. A dairy chain can involve production, processing, packaging, transport, storage and retailer. Activities require inputs such as raw materials, and human contribution which are employed to add value and to transport dairy products to the consumers.

In this study we mapped the entire supply chain of company A and grouped it to eight categories to simplify the analysis of the process and risk assessment, presented in the following figures:

Figure 4:3: Supply Chain of the Milk Product

Figure 4:4: Supply Chain Map of the Yogurt Product

Figure 4:5: Supply Chain Map of the Cheese Product

Figure 4:7: Supply Chain Map of the Ice-Cream Product

Figure 4:6 Output process

The first three categories of feeding, milking and heating in Figure 4:3 are common among all products, because all the products of our case study are made from heated and pasteurized milk. Therefore, as it is clear in this figure, the supply chain starts with the feeding process group, following by milking process and afterward the heating process. In the follow there are more detailed description of each product group and their supply chain process.

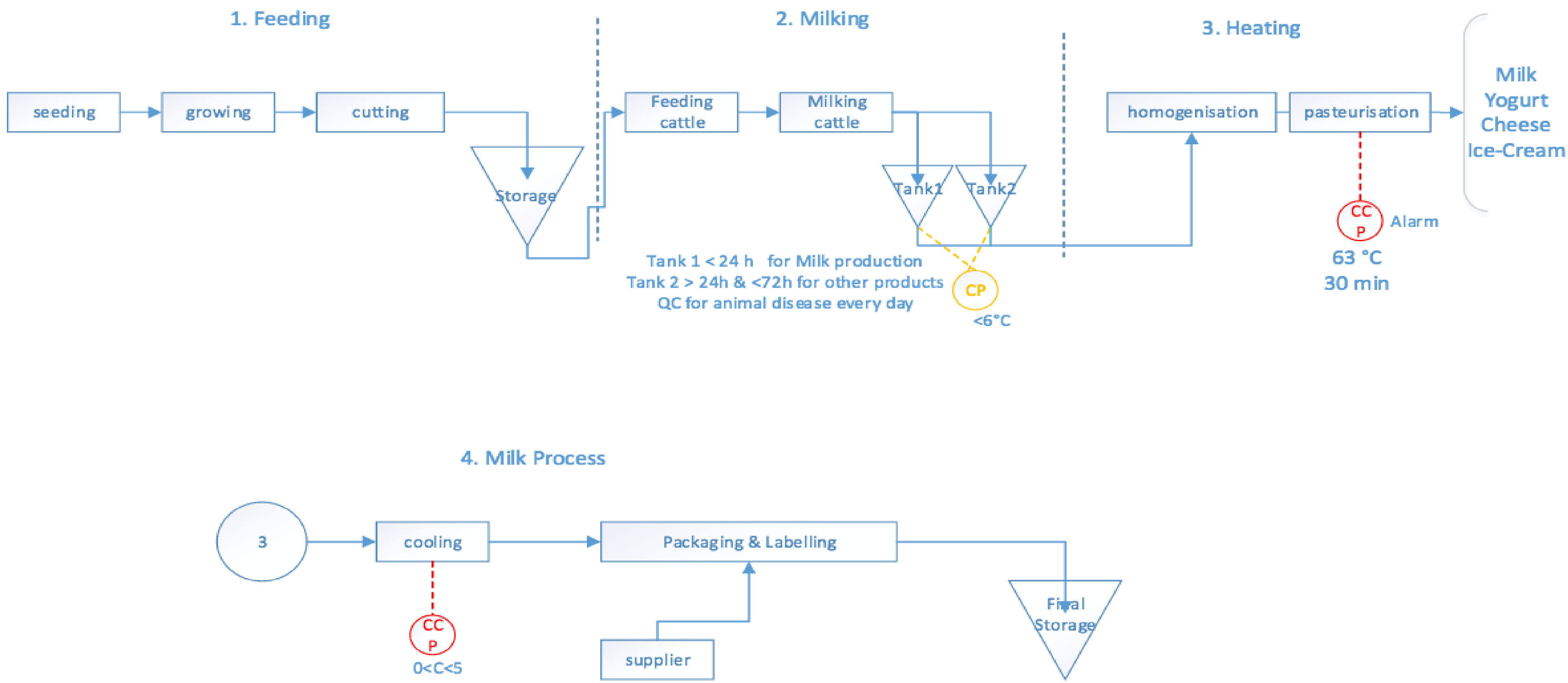

Figure 4:3: Supply Chain of the Milk Product

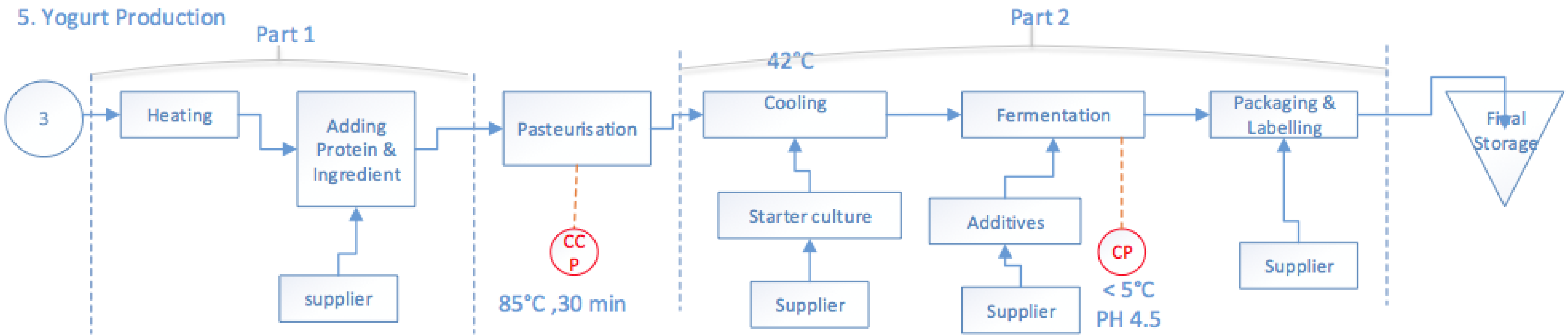

Figure 4:4: Supply Chain Map of the Yogurt Product

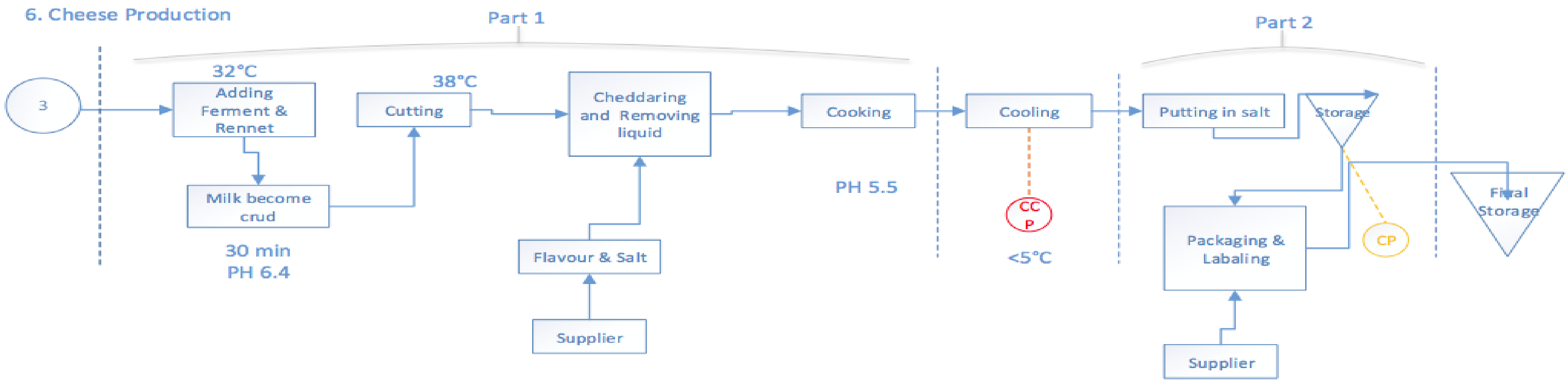

Figure 4:5: Supply Chain Map of the Cheese Product

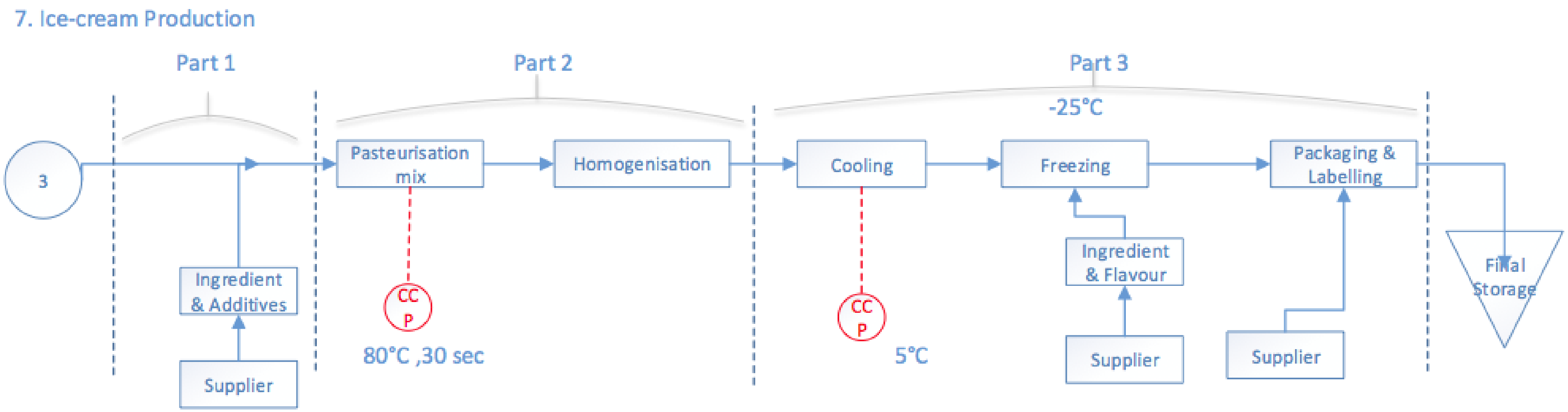

Figure 4:7: Supply Chain Map of the Ice-Cream Product

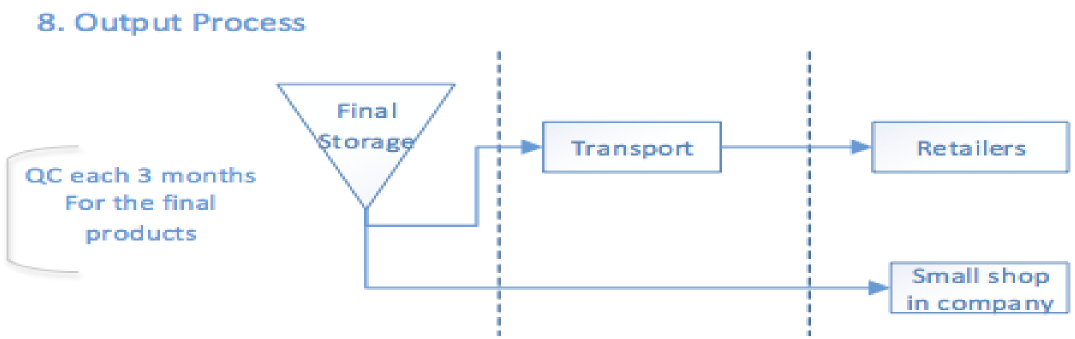

Figure 4:6 Output process

4.2.2 Milk Production

1. **Feeding Process**

The objective of good dairy farming practice is the on-farm production of safe, quality milk from healthy animals under generally acceptable conditions. To achieve this end, dairy producers need to apply Good Agricultural Practice (GAP). Animal health and quality feeding is one of the main principle in GAP and it is one of the constraint for SMEs. Overcoming this constraint could significantly improve productivity and result in real and direct benefits for producers. Good dairy farming practices for animal health are establishing the herd with resistance to disease; preventing the entry of disease on to the farm; establishing effective health management; and using all chemicals and veterinary medicines as directed.

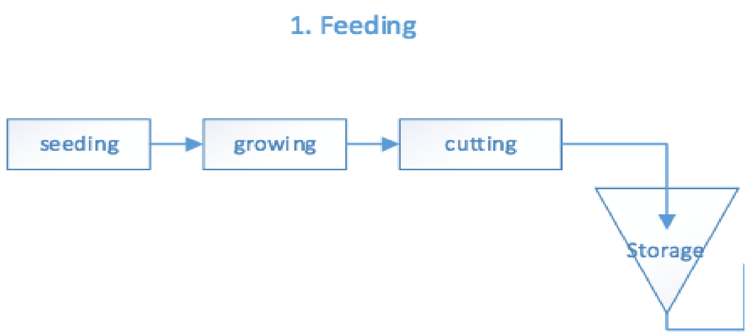

Figure 4:8: Feeding process

In our case company A the production of the cattle feeds, that is an agricultural production, in a simplified perspective (Figure 4:8) includes seeding, growing and cutting of the cattle’s feeding products. Entire production is performed in a farm beside the company A under the company’s control and operation. The cattle feeds are produced once a year and stocked in the storage located in the farm. In case of shortage in feeding material, extra feeds can be purchased from external suppliers as well. Therefore, majority of the required cattle feeds are controlled and process by the company A.

The end cattle feeding products undergo pathogen test to control any chemical or biological hazard within the feeds. Feeding products are one of the principle factors in fresh milk contamination; however, the probability of this risk is relatively low in this step of the chain in our case company, due to the safety control and high quality production of feed inside the company.

Hazards Identification:

According to the literature and historical food outbreaks summarized in Figure 4:2 the main hazards in this stage (raw product/ingredient/pre-processing) that are also relevant to company A are as follows:

There are four main source of hazards as Colonized/infected animal, Contamination by workers, Food contamination, and Water contamination. As it is clear in the Figure 4:2 the probability of these hazards are “Source of contamination, but likely to be destroyed during subsequent processing” because all the products are pasteurized. And according to Figure 4:2and Table 3:2: Probability Index of failure index 1 is assigned to each of these hazards and then adding the total probabilities together.

Table 4:5: Probability index of feeding process

Hazards	Sign in Figure 4:9.	Probability Index
Colonized/infected animal	—	1
Contamination by worker	—	1
Food contamination	—	1
Water contamination	—	1
Cumulative Index of Failure		4

2. **Milking Process**

The process of milking (Figure 4:10) involves feeding the cattle, milking cattle using mechanical machine and storage of fresh milk into two tanks (tank 1, and tank 2). Thank 1 is used for the production of milk product and the storage milk can be kept up to 24 hours. The second tank (tank2) is used for the other products (Cheese, yogurt, ice-cream) and the time of storage is between 24 hours and 72 hours. The temperature of both tanks should be less than 6°C, which is a critical point in the HACCP plan and it is measured and monitored by an automatic temperature measurement.

Milking machines keep the milk enclosed and safe from external contamination. The interior 'milk contact' surfaces of the machine are kept clean by a manual or automated washing procedures implemented after milking is completed. Milk contact surfaces must comply with regulations requiring food-grade materials (typically stainless steel and special plastics and rubber compounds) and are easily cleaned.

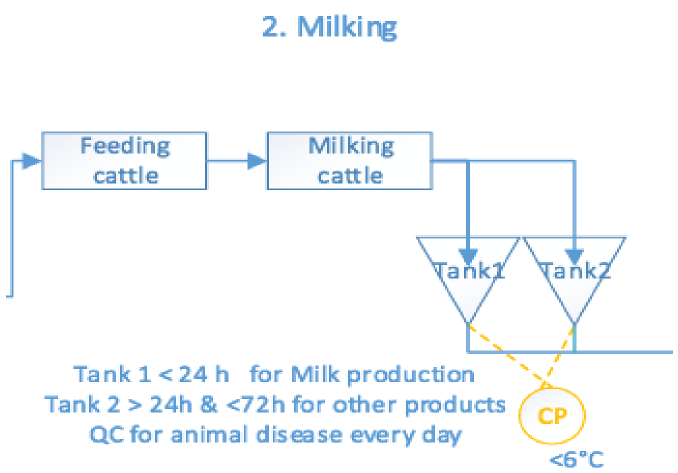

Figure 4:10: Milking Process

Hazards identification:

According to Figure 4:2 the main hazards in this step (processing or preparation) that are applicable in our case study A are as presented in Table 4:6. The method for assigning the probability index is the same as Feeding process.

Table 4:6: Probability index of milking process

Hazards	Sign in Figure 4:11.	Probability Index
Contamination by worker	▲	3
Cleaning of milking equipment	●	2
Cleaning of milking tanks	▲	3
Improper Cooling tanks	■	4
Cumulative Index of Failure		12

3. Heating Process

The next stage of dairy production in company A is heat processing in Figure 4:12. This stage includes homogenization and pasteurization.

The fat in milk is in globules of different size, varying from 0.20 to 2.0 µm. The non-uniform size of the globules makes the cream, to the top of the milk container. Homogenization aims to reduce the milk fat globules size to less than 1.0 µm and makes them to distribute evenly in milk. Homogenization makes the milk more uniform and not-homogenized milk is sometimes called “cream-line” milk. Pasteurized milk does not essentially need to be homogenized, but homogenized milk must be pasteurized to inactivate native enzymes that cause rancidity, which causes short shelf life in milk and off-flavors. Homogenization process breaks up the globules using high pressure to force milk at a high velocity through a small orifice. Therefore, the outcome of homogenization is increasing the number of fat globules but in a smaller size.

Pasteurization is the process of heating a liquid under the boiling point to inactivate microorganisms. New pasteurization process which is in use today, heats up the milk to 145°F (62.8°C) for 30 minutes in batch process, or 161°F (71.7°C) for 15 sec in continuous process, to kill the microorganisms. Processing conditions for temperatures above 200°F (93°C), are rarely used because they can impart an undesirable cooked flavor to milk.

Pasteurization process could be done in a batch or a continuous process. In company A the milk is pumped from the raw milk tank 1, 2 into the holding tank that feeds into the batch homogenization and pasteurization system. Then the milk is heated to the proper temperature and stayed at that temperature for the appropriate time (63°C) for 30 minutes and then cooled. Afterward, the cooled milk is pumped out of the container to the processing line, for instance to the cheese vat or packaging station.

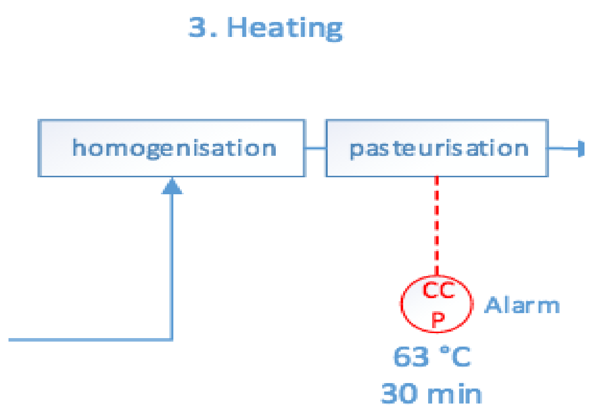

Figure 4:12: Heating process

The entire process performs automatically using pipelines and heating machines, and the time and temperature of the pasteurization process is among Critical Control Point (CCP) of HACCP guidelines that is measured and monitored by a control system. In case of failure in the time and temperature the alarm system works to inform the operators for the proper reaction. After the process the pasteurized milk is ready to be used in all the other products in the company.

Hazards Identification:

Similar to the previous sections (feeding, and milking) and according to Figure 4:2 the main hazards in this step (processing or preparation) that are applicable in our case study are as follows:

Table 4:7: Probability index of heating process

Hazards	Sign in Figure 4:13.	Probability Index
Heating process failure	■	4
Cleaning of equipment	▲	3
Improper Cooling	■	4
Cumulative Index of Failure		11

4. Milk Process

Milk, as defined by the U.S. Code of federal Regulations (CFR), 21 CFR 133.3, is: "the lacteal secretion, practically free from colostrum, obtained from the complete milking of one or more healthy cows which may be clarified and may be adjusted by separating part of the fat…". (CFR, 2015) Milk that is in its final package for beverage consumption must be pasteurized or ultra-pasteurized, and must include not less than 8.25% solids and not less than 3.25% milk fat. Milk could be adjusted by skimming the milk fat, or by adding cream, nonfat dry milk, or dry whole milk. (CFR, 2015)

Figure 4:14 shows the production of the pasteurized milk (full cream and skim); the pasteurized milk from previous process (process 3) follows a pipeline and enters the cooling system. Cooling process is a CCP and temperature should be controlled (0<C<5) °. Then the cooled milk pumps to the packaging system, and the processed milk packs and labels through a fully automated machine. Packaging and labeling materials purchase from external supplies and an operator has a visualize monitoring of the packaging process to control the accuracy of the packaging process. At the end the packed product transports manually to the final storage. (Bylund & Pak, 2003)

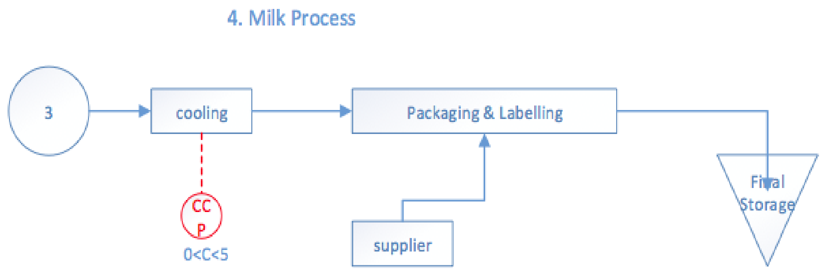

Figure 4:14: Milk process

Hazards Identification:

According to Figure 4:2 the main hazards in this step (processing or preparation) that are applicable in our case study are as follows:

Table 4:8: Probability index of mik process

Hazards	Sign in Figure 4:15.	Probability Index
Improper cooling	■	4
Cleaning of equipment	▲	3
Room temperature holding	■	4
Cumulative Index of Failure		11

Output process:

The output process for all the products in company is the same (Figure 4:16). It starts with entering the products into final storage, keeping for a predefined time schedule and under temperature control, then transporting by refrigerator trucks to the retailers. There is also a small shop in the farm that sells the low quantity of the fresh products to the local customers.

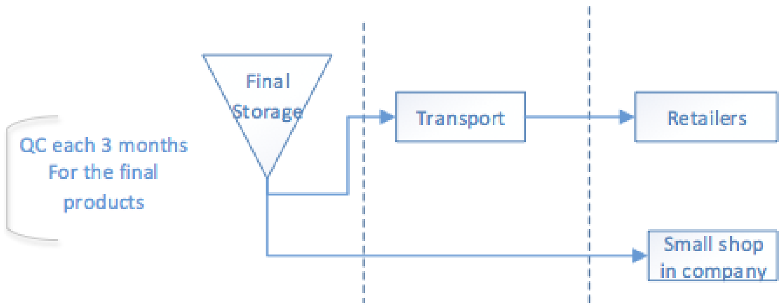

Figure 4:16: Output process

Hazards Identification:

Hazard identification for output process is the same in all products, and according to Figure 4:2 the main hazards in this step (Storage, Transport, and Retailer) that are applicable in our case study are as follows:

Table 4:9: Probability index of output process

Hazards	Sign in Figure 4:17.	Probability Index
Improper refrigerator in Storage/Transport/Retailer	■	4
Cumulative Index of Failure		4

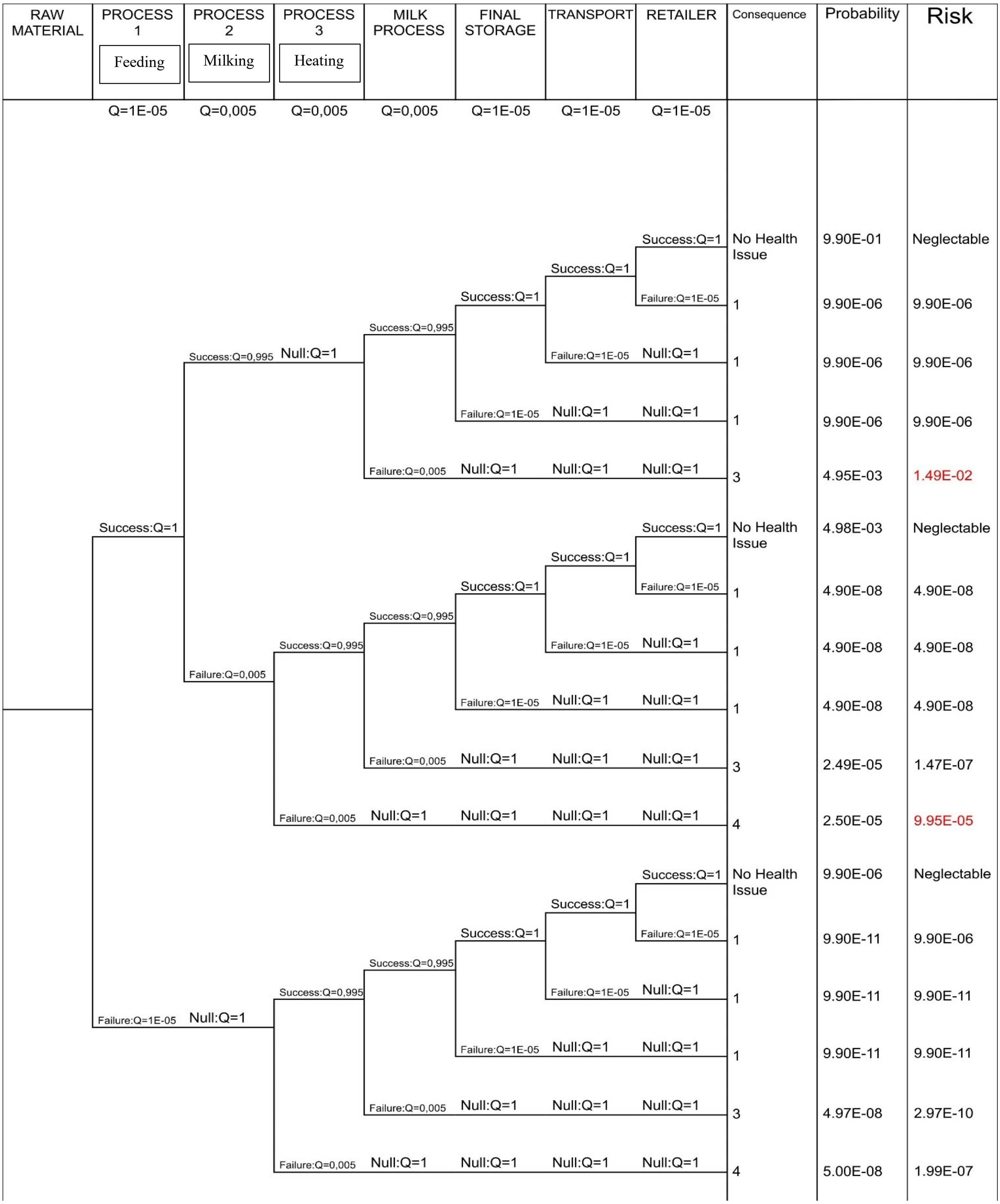

Figure 4:18: ETA of Milk production supply chain

Results of the ETA (Milk Production):

From the Event Tree (Figure 4:18) two pathways (sequences) have been identified with high risk (section 3.1.2.) In order to recognize where along the supply chain there are critical steps the KPIs have been used as follow:

1. In the first sequence with the total probability of 4,95E-03 and consequence of 3, the Risk is 1,49E-02. the steps (Process 1, Process 2) are performed successfully (i.e. without safety failure) however, there is failure in Milk Process, and consequently the following steps of Final Storage, Transportation, and Retailer might not effect on the consequence, thus they are considered as Null (No Success, No Failure). The reason is that if there is any contamination in the milk process, then following steps could not reduce this hazard and it might not increase the hazards to the next level (4) as well. Furthermore, as in this sequence all the early steps of Raw Material, Process 1, Process 2 are supposed to be success the Process 3 (Pasteurization) is also Null, and it means the success and failure of process 3 could not impact on the final results.

However, as it is clear in the Figure 4:3: Supply Chain of the Milk Product, involves process 1, 2, 3, 4, and 8. It means Feeding, milking, heating, milk process, and output process (final storage, transport, retailers). Using ETA, Milk process (Figure 4:14) identified as high risk and it consists of Cooling, and Packaging operation. In this process production and supplier KPIs are applicable. And based on the KPIs model and gathered data from company A we have:

Process 2 (Milking Process): involves supplier, production

Table 4:10: KPI measurement of Process 2 (involves supplier, production)

KPI	KPI index	Weight	Results
S1	A	4	200
S2	B	3	60
S3	B	4	80
S4	B	3	60
S5	D	3	-60
Σ KPI Indicator			340
KPI	KPI index	Weight	Results
P1	B	4	80

P2	A	3	150
P3	B	2	40
P4	B	4	80
P5	D	3	-60
Σ KPI Indicator			290

2. In the second sequence with the total probability of 2,5E-5 and Consequence of 4, and risk of 9,95E-5; we have success in Process 1 (Feeding) and failure in Process 2 (Milking) and Process 3 (Heating). The following events of Milk Process, Final Storage, Transportation, and Retailer might not effect on the final consequence, thus they are considered as Null.

Process 2 is Milking process that consists of Feeding, Milking, and Storage in Tanks. Process 3 includes homogenization and pasteurization. In these processes, supplier, production, and storage are involved and in order to recognize which part of these events has highest risk we need to apply the KPIs measurement similar to previous section.

Table 4:11: KPI measurement of process 3 (Heating: involves production)

KPI	KPI index	Weight	Results
P1	A	4	200
P2	D	2	-40
P3	B	2	40
P4	B	2	40
P5	D	3	-60
Σ KPI Indicator			180

Table 4:12: KPI measurement of Milk process (involves supplier, production)

KPI	KPI index	Weight	Results
S1	A	3	150
S2	A	3	150
S3	A	4	200
S4	E	3	-150
S5	C	2	0

Σ KPI Indicator			350
KPI	KPI index	Weight	Results
P1	D	3	-60
P2	C	1	0
P3	A	4	200
P4	A	4	200
P5	D	2	-40
Σ KPI Indicator			300

Results and recommendation:

As mentioned earlier according to the ETA the first high risk sequences above threshold is due to failure in Milk Process that consists of Production, and Supplier of packaging materials. And based on KPIs measurement above, we could see the Production has lower safety index (300) comparing with Supplier (350). The second high risk sequences (more than threshold) is due to failure in Milking Process that consists of Feeding, Milking, and Storage in Tanks. And failure in Process 3 includes homogenization and pasteurization. The KPIs show the lowest safety index belongs to operation of heating (180), comparing to production of milking (290) and supplier of the milking process (340). Therefore, we can identify the most critical point along the milk supply chain is the operation of the Heating (homogenization and pasteurization) and Milk Process (cooling and packaging). This result is in alignment with the food outbreaks as well, because contamination of the Milk product after pasteurization could be at high risk and this risk might not be reduced or eliminated in the following steps. Moreover, pasteurization in process 3 is fundamentally important in terms of safety of the dairy products. Therefore, applying control points and checking is this sections is recommended to reduce the probability of failure.

4.2.3 Yogurt Production

Yogurt Process:

"Yogurt is a fermented milk product that contains the characteristic bacterial cultures Lactobacillus bulgaricus and Streptococcus thermophilus. All yogurts must contain at least 8.25% solids not fat.

Full fat yogurt must contain not less than 3.25% milk fat, low fat yogurt not more than 2% milk fat, and nonfat yogurt less than 0.5% milk". (CFR, 2015)

The following process flow and discussion provide a general outline of the steps required for making yogurt (Figure 4:19).

In yogurt process (process 5) pasteurized milk from process (3) heats up and adjusts to reach the desired solids and fat content. To raise the amount of whey protein and provide a desirable texture, dry milk is added to the content. At this point, Ingredients such as stabilizers are added as well. Afterward, the milk blend is pasteurized at 185°F (85°C) for 30 minutes or at 203°F (95°C) for 10 minutes, in order to denature the whey protein. The high heat treatment allows the proteins to form a more stable gel, and prevents separation of the water during storage. It also decreases the number of spoilage organisms in the milk to provide a better environment for the starter cultures to grow. The mixture is homogenized (2000 to 2500 psi) to blend all ingredients completely and increase yogurt consistency. The milk is cooled to 108°F (42°C) until a pH 4.5 is reached to bring the yogurt to the ideal growth temperature for the starter culture. The starter cultures are added after pasteurization to ensure that the cultures remain active in the yogurt after fermentation to act as probiotics. This allows the fermentation to growth to form a soft gel and the characteristic flavor of yogurt that could take several hours.

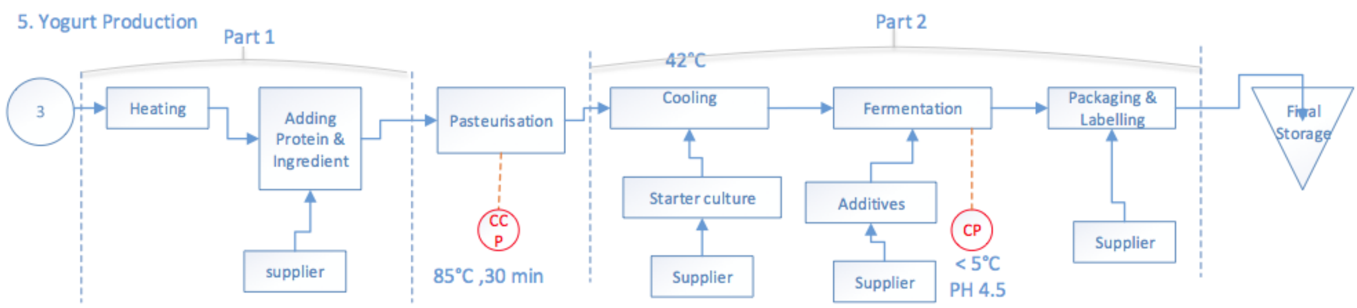

Figure 4:19: Supply Chain of the Yogurt Product

Then yogurt is cooled down to 5°C to stop the fermentation process. In this step the flavors are added at special time depending on the kind of yogurt. Afterward, the yogurt fills into package and labels using automated machine with visual control of the operator, and gets ready to transport into the final storage.

Hazards Identification:

According to Figure 4:2 the main hazards in this step (processing or preparation) that are applicable in company A are as follows:

Table 4:13: Probability index of part 1

Hazards	Sign in Figure 4:20.	Probability Index
Contamination by worker	▲	3
Cleaning of equipment	▲	3
Contamination by ingredient	■	4
Cumulative Index of Failure		10

Table 4:14: Probability index of part 2

Hazards	Sign in Figure 4:21.	Probability Index
Contamination by worker	■	4
Improper Cooling	▲	3
Organism/toxin survives process	■	4
Cumulative Index of Failure		11

Table 4:15: Probability index of pasteurization

Hazards	Sign in Figure 4:22.	Probability Index
Heating process failure	■	4
Cleaning of equipment	■	4
Cumulative Index of Failure		8

Output process:

Output process is presented in Figure 4:16. And the results of cumulative index of failure is similar to Table 4:9: Probability index of output process and equal to 4.

And using the Table 3:3: Quantitative military index for probability of failure, we can assign the quantitative index of failure probability for each event of ETA (Figure 4:23).

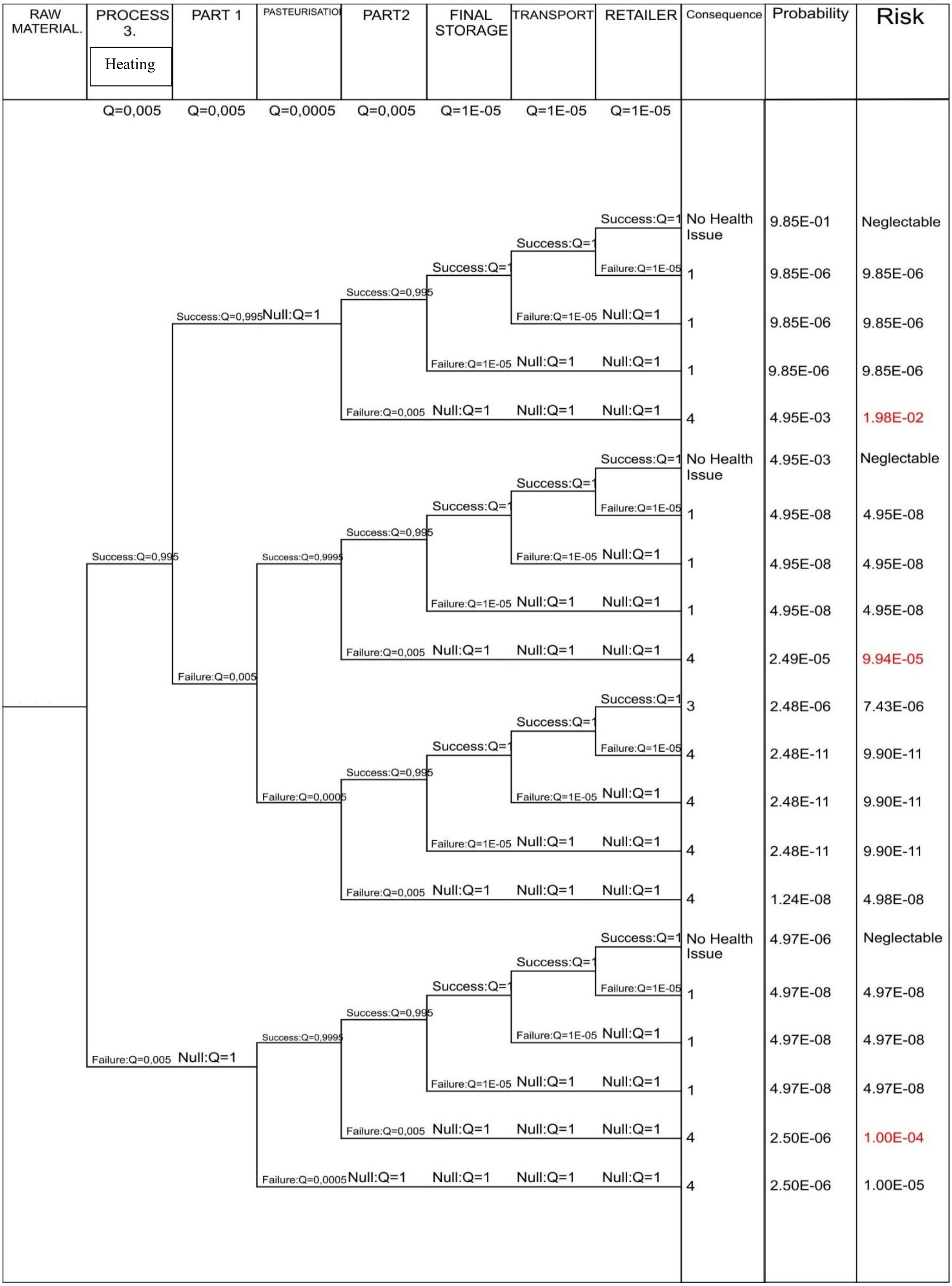

Figure 4:23: ETA of yogurt supply chain

Results of the ETA:

From the Event Tree Analysis (Figure 4:23) three pathways have been identified with high risk In order to recognize where along the supply chain there are critical steps KPIs have been used as follow:

1. In this first pathway the steps Process 3, Part 1 are performed successfully (i.e. without safety failure). However, there is failure in Part 2, and consequently the following steps of Final Storage, Transportation, and Retailer might not effect on the consequence, thus they are considered as Null (No Success, No Failure). The reason is that if there is any contamination in Part 2, then following steps could not reduce this hazard and it might not increase the hazards to more than level 4. The same logic is applied in the next event as well, because failure in Part 2 after pasteurization could results in worst consequence (4). This pathway has the total probability of 4,95E-03 and Consequence of 4, that means the Risk (Probability*Consequence) of 1,98E-02.

Part 2, Figure 4:19, consists of Cooling, Fermentation, adding Additives, Packaging and Labelling. In this process, suppliers (for additives and packaging materials) and production are involved and in order to recognize which part has highest risk we need to apply the KPIs measurement.

Table 4:16: KPI measurement of yogurt process (involves supplier, production)

KPI	KPI index	Weight	Results
S1	A	3	150
S2	A	3	150
S3	A	4	200
S4	E	3	-150
S5	C	3	0
Σ KPI Indicator			350
KPI	KPI index	Weight	Results
P1	B	3	60
P2	C	1	0
P3	A	4	200
P4	A	4	200
P5	D	3	-60
Σ KPI Indicator			400

Thus, the supplier has the lower KPI index (350)

2. In this second pathway the steps Process 3, and Pasteurization are performed successfully (i.e. without safety failure). However, there is failure in Part 1 and Part 2, and consequently the following steps of Final Storage, Transportation, and Retailer might not effect on the consequence, thus they are considered as Null (No Success, No Failure). With total probability of 2,486E-05 and Consequence of 4, that means the Risk (Probability*Consequence) of 9,94E-05.

Part 1 consists of Heating, Adding protein, and ingredient. Part 2 includes Adding Starter culture, Cooling, Fermentation and Packaging. In this process, suppliers (for protein, ingredient and packaging materials) and production are involved and in order to recognize which part has highest risk we need to apply the KPIs measurement. The results of KPIs are the same as pathway 1, because in both sequences we have failure in Cheese process section with the same KPIs measures. Thus, in this pathway supplier has the lowest safety index (350) as well.

3. In the third pathway the Process 3, and Part 2 have failure, and Pasteurization is successful. Consequently the following steps of Final Storage, Transportation, and Retailer might not effect on the consequence, thus they are considered as Null. With total probability of 2,499E-05 and Consequence of 4, that means the Risk (Probability*Consequence) of 1,0E-04.

Process 3 (Heating) includes homogenization and pasteurization. Part 2 includes Adding Starter culture, Cooling, Fermentation and Packaging. The results of KPIs for these two sections are as follow:

Process 3 (Heating): KPI index (180) (Table 4:11)

Part 2: KPI index (350) (400) (Table 4:14)

Therefore, the lowest KPI index belongs to Process 3 (180).

Final results:

As mentioned earlier according to the ETA, we have three high-risk sequences. These pathways are due to failure in Part 2, and then Part 1 plus Part 2, and Process 3 plus Part 2. Measuring the KPI in each pathway, we can summaries that in first two pathways supplier has the lowest safety index, and in third pathway heating process is the lowest safety point.

Therefore, we can identify the most critical point in the Yogurt Production supply chain that is intervention of supplier in Part 1 and Part 2 of yogurt process as well as operation in Heating process

(process 3). It means the supply of materials for ingredient, starter culture, additives and packaging; beside the process of raw milk pasteurization are critically important. This result is in alignment with the food outbreaks as well, because contamination of the Yogurt product due to failure in pasteurization and after pasteurization due to mixture with other raw materials during the process could be at high risk and this risk might not be reduced or eliminated in the following steps. Therefore, setting more accurate control point in Heating process and quality checking of raw materials provided by suppliers are critical and recommended to reduce the probability of failure, and consequently reduction of the final risk of safety for consumers.

4.2.4 Cheese Production

Cheese Process:

Cheese product could be in many varieties. This diversity determines the processing, characteristics, Flavors, and ingredients of the cheese. Cheese can be made from raw or pasteurized milk, however, in company A only pasteurized milk is used to produce cheese. For rennet cheeses, calf rennet or, rennet produced through microbial bioprocessing is used. Some common ingredients comprise hot and sweet peppers, herbs, and horseradish. The following process describes a general plan of cheese making steps (Figure 4:4).

Milk is cooled after pasteurization (process 3) to 90°F (32°C) to bring it to the temperature needed for the starter bacteria to grow. The rennet is the enzyme that acts on the milk proteins to form the curd. After the rennet is added, the curd is not disturbed for approximately 30 minutes so a firm coagulum forms. The curd is allowed to ferment until it reaches pH 6.4. The curd is then cut into small pieces and heated to 100°F (38°C). The heating step helps to separate the whey from the curd. The curd mats are cut into sections and piled on top of each other and flipped periodically. This step is called Cheddaring. Cheddaring helps to expel more whey, allows the fermentation to continue until a pH of 5.1 to 5.5 is reached, and allows the mats to "knit" together and form a tighter matted structure. The curd mats are then milled (cut) into smaller pieces. For cheddar cheese, the smaller, milled curd pieces are put back in the vat and salted by sprinkling dry salt on the curd and mixing in the salt. In some cheese varieties, such as mozzarella, the curd is formed into loaves and then the loaves are placed in a brine (salt water solution).

The cheese is stored in coolers until the desired age is reached. Depending on the variety, cheese can be aged from several days to several months. Then the cheese is ready to pack and labeled and transport to the final storage.

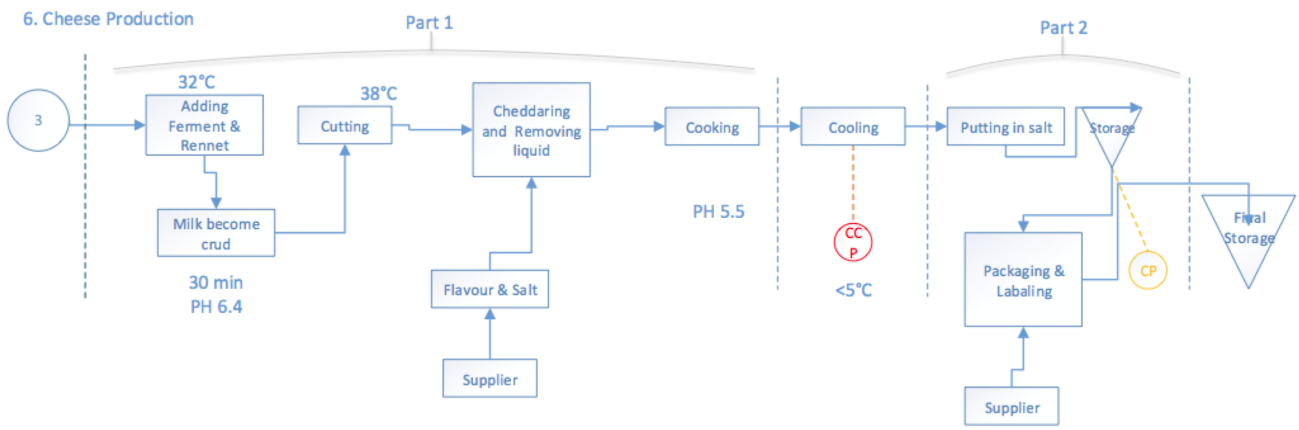

Figure 4:5: Supply Chain Map of the Cheese Product

Hazards Identification:

According to Figure 4:2 the main hazards in this step (processing or preparation) that are applicable in our case study are as follows:

Table 4:17: Probability index of Part 1

Hazards	Sign in Figure 4:24.	Probability Index
Contamination by worker	■	4
Cleaning of equipment/environment	▲	3
Room temperature	—	1
Cooking	—	1
Contamination by adding materials	—	1
Cumulative Index of Failure		10

Table 4:18Probability index of Part 2

Hazards	Sign in Figure 4:25.	Probability Index
Contamination by worker	■	4
Cleaning of equipment/environment	▲	3
Room temperature	—	1
Organism/toxin survives process	■	4
Cumulative Index of Failure		12

Table 4:19: Probability index of Cooling process

Hazards	Sign in Figure 4:26.	Probability Index
Contamination by worker	■	4
Cleaning of equipment/environment	▲	3
Room temperature	—	1
Cumulative Index of Failure		8

Output process:

Figure 4:16: Output process, and the hazard identification is the same as milk product.

The probability index is 4, Table 4:9.

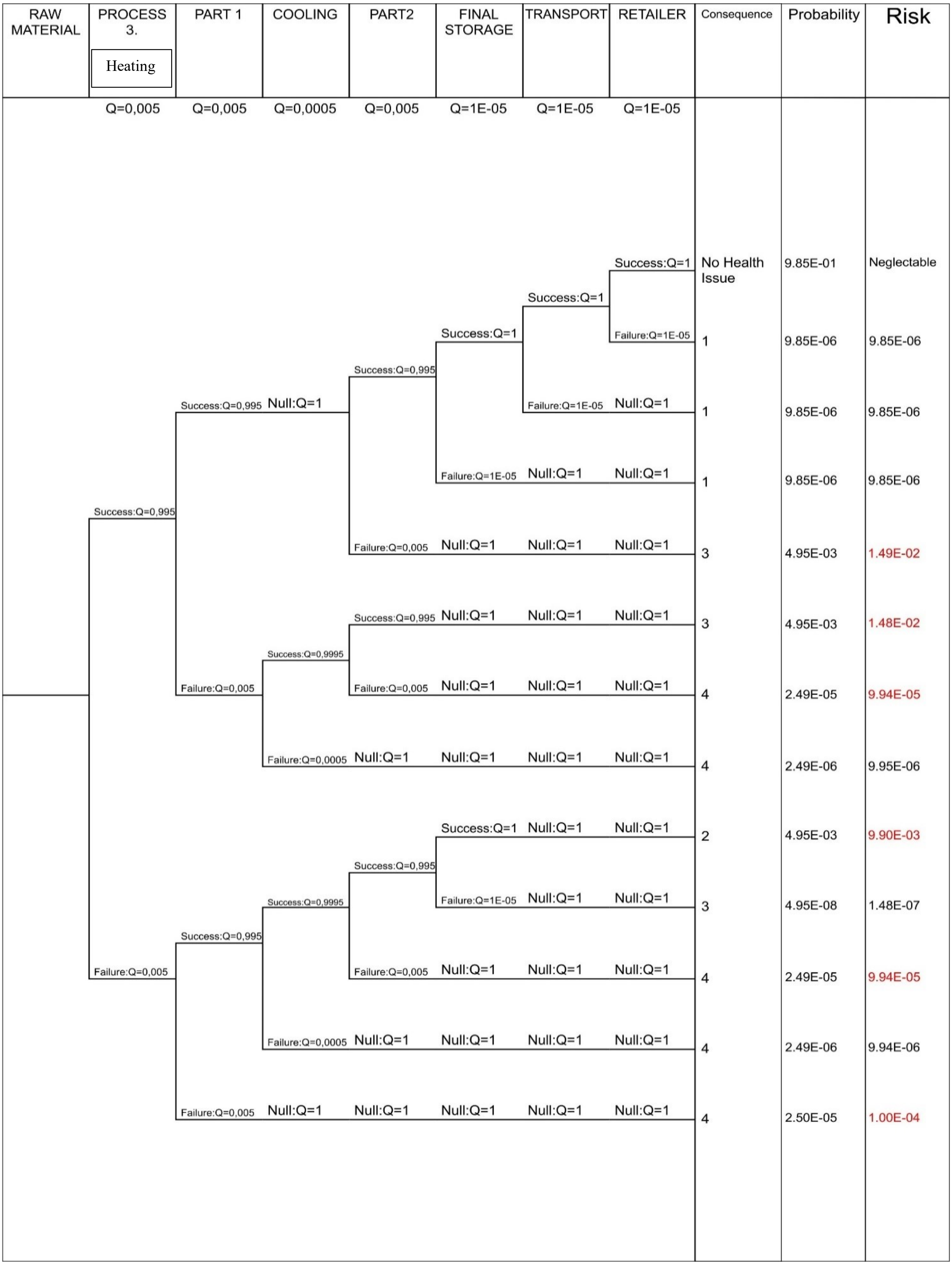

Figure 4:27: ETA of cheese supply chain

Results of the ETA:

From the Event Tree Analysis (Figure 4:27) six pathways have been identified with high risk. The logic of assigning null for some events is the same as previous products (e.g. Milk, Yogurt) as they do not have major impact on the final consequences, neither increase nor decrease the severity levels. Furthermore, in each of these sequence there could be involvement of more than one supply chain stage (i.e. supplier, production, inventory, etc.). Thus, we need to measure the KPIs in each sequence in order to identify the critical point for intervention and reducing the risk.

1. Success in Process 3, Part 1, failure in Part 2, and Null in Cooling, Final storage, Transportation, Retailer. The total probability of 0,000495 and severity of 3, therefore the Risk (Probability*Consequence) of 1,49E-02.

Part 2 includes aging of the cheese product and packaging them. In this process, suppliers (for packaging) and production are involved and in order to recognize which part has highest risk we need to apply the KPIs measurement.

Table 4:20: KPI measurement of Part 2 (involve supplier, production)

KPI	KPI index	Weight	Results
S1	A	3	150
S2	A	3	150
S3	A	4	200
S4	E	3	-150
S5	C	4	0
Σ KPI Indicator			350
KPI	KPI index	Weight	Results
P1	D	3	-60
P2	C	1	0
P3	A	4	200
P4	A	4	200
P5	D	3	-60
Σ KPI Indicator			280

2. Success in Process 3, failure in Part 1, success in Cooling, success in Part2, null in final storage, transportation and retailer. The total probability of 4,95E-03 and severity of 3, therefore the Risk (Probability*Consequence) of 1,48E-02.

Part 1 consists of Adding ferment and rennet, cutting, adding flavor and salt, and cooking. In this process, suppliers (for additives) and production are involved and the result of KPIs measurement is the same as previous pathway, because both have happened in the same process and unit of production.

3. Success in Process 3, failure in Part 1, success in Cooling, failure in Part2, null in final storage, transportation and retailer. The total probability of 2,486E-05 and severity of 4, therefore the Risk (Probability*Consequence) of 9,94E-05.

The results of KPIs in Part 1 and Part 2 have been mentioned above and the same is applicable here.

4. Failure in Process 3, success in Part 1, Cooling, Part2, and final storage, null in transportation and retailer. The total probability of 4,95E-03 and severity of 2, therefore the Risk (Probability*Consequence) of 9,90E-03.

Process 3 (Heating) as mentioned in previous section consists of homogenization and pasteurization. The results of KPIs show the lowest KPI index belongs to the production.

Table 4:21: KPI measurement of Process 3 (involve production)

KPI	KPI index	Weight	Results
P1	A	4	200
P2	D	2	-40
P3	B	2	40
P4	B	2	40
P5	D	3	-60
Σ KPI Indicator			180

5. Failure in Process 3, failure in Part 1, null in Cooling, Part2, final storage, transportation and retailer. The total probability of 2,5E-05 and severity of 4, therefore the Risk (Probability*Consequence) of 1E-04.

The lowest KPIs index belongs to operation of Process 3 (180) by comparing the KPI of Process 3 (180), Part 1 (350), (280).

6. Failure in Process 3, success in Part 1, success in Cooling, failure in Part2, null in final storage, transportation and retailer. The total probability of 2,486E-05 and severity of 4, therefore the Risk (Probability*Consequence) of 9,94E-05.

The KPIs results are the same as pathway 5, as Part 1 and Part 2 have the same KPI results.

Final results:

Based on the ETA we have six sequences with risk above threshold. The ETA shows that in these sequences failures occur in Process 3, Part 1, and Part2 singular or in combination. These sections involve interference of Production, Supplier and Storage. Therefore, we measured the KPIs in these parts and based on KPIs data, we can identify production has the lowest KPI index in the Process 3 (180) Part 1 (280) and Part 2 (280). Therefore, we can identify the most critical point in the Cheese Production supply chain is process of Pasteurization of raw milk and then process of Part 1 and Part 2 in cheese process. This result is also confirmed by the food outbreaks as well, because failure of the pasteurization results in non-pasteurized cheese products that is one of the main sources of cheese safety outbreaks. Contamination of the cheese product after pasteurization could be at high risk as well and it could be associated with contamination with human contact during the process and this risk might not be reduced or eliminated in the following steps. Therefore, applying control points in these two stages and having more accurate quality checking beside food safety training for staff who are in direct contact with products are critical and recommended to reduce the probability of failure, and consequently reduction of the final risk of safety for consumers.

4.2.5 Ice-Cream Production

Ice-Cream Process:

“Ice cream is a frozen blend of a sweetened cream mixture and air, with added flavorings.” There are a wide variety of ingredients, formulations (recipes), and milk fat, milk solids (protein + lactose + minerals) that are commonly used in ice cream. The following process provides a general outline of the steps required for producing the ice cream.

The pasteurized milk (process 3), mix with nonfat solids, stabilizers and emulsifiers, to provide complete mixing of dry ingredients and liquid. Ice cream mix is pasteurized at 176°F (80°C) for 30 sec. The conditions for pasteurizing ice cream mix are higher than fluid milk due to increased viscosity from sweetener content, more fat, solids and the egg yolks adding into the products.

In next step the ice cream mix is homogenized to reduce the milk fat globule size and make a better emulsion and contribute to a creamier and smoother ice cream. Homogenization also ensures that the stabilizers and emulsifiers are well mixed and distributed consistently in the ice cream blend before it is frozen. Ice cream mix then is aged at 40°F (5°C) for at least 4 hours or overnight. Aging the blend makes the milk fat to crystallize partially and provides time to hydrate for the proteins stabilizers. This increases the whipping properties of the mixture. Before freezing the mix, only ingredients that are liquid, and colors could be added to ensure the mix flows properly through the freezing equipment.

Afterward, the ice cream blend is pumped to the freezing container and the air is combined with another pump just before it enters the freezing container. Any bulky kind of flavorings such as fruits, nuts, candies are added at this point because these ingredients cannot be added before freezing due to interfere with the smooth flow of the mix.

Then the ice cream is cooled down quickly to a holding temperature of -13°F (-25°C). The time and temperature of cooling depends on the kind of storage freezer. Quick cooling will cause rapid freezing of water and produce small ice crystals. Storage at -13°F (-25°C) can help to maintain the ice crystals and increase product quality.

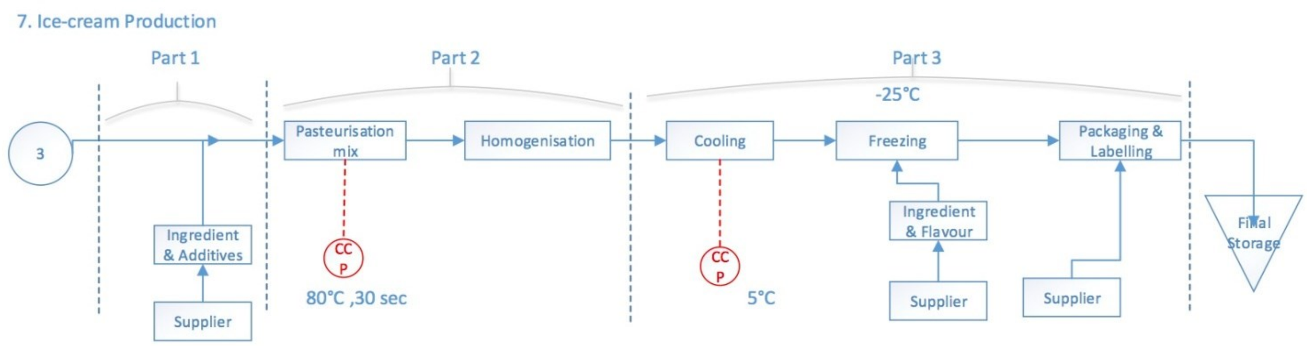

Figure 4:7: Supply Chain Map of the Ice-Cream Product

Hazards Identification:

Based on Figure 4:2 the main hazards in this step (processing or preparation) that are applicable in our case study are as follows:

Table 4:22: Probability index of of part 1

Hazards	Sign in Figure 4:28.	Probability Index
Contamination by worker	■	4
Cleaning of equipment/environment	▲	3
Contamination by ingredient	—	1
Cumulative Index of Failure		8

Table 4:23: Probability index of of part 2

Hazards	Sign in Figure 4:29.	Probability Index
Improper Cooling	■	4
Cleaning of equipment/environment	▲	3
Organism/toxin survives process	■	4
Cumulative Index of Failure		11

Table 4:24: Probability index of pasteurization mix

Hazards	Sign in Figure 4:30.	Probability Index
Heating process failure	■	4
Cleaning of equipment	▲	3
Cumulative Index of Failure		7

Output process:

The results are the same as Figure 4:16: Output process, and Table 4:9: Probability index of output process.

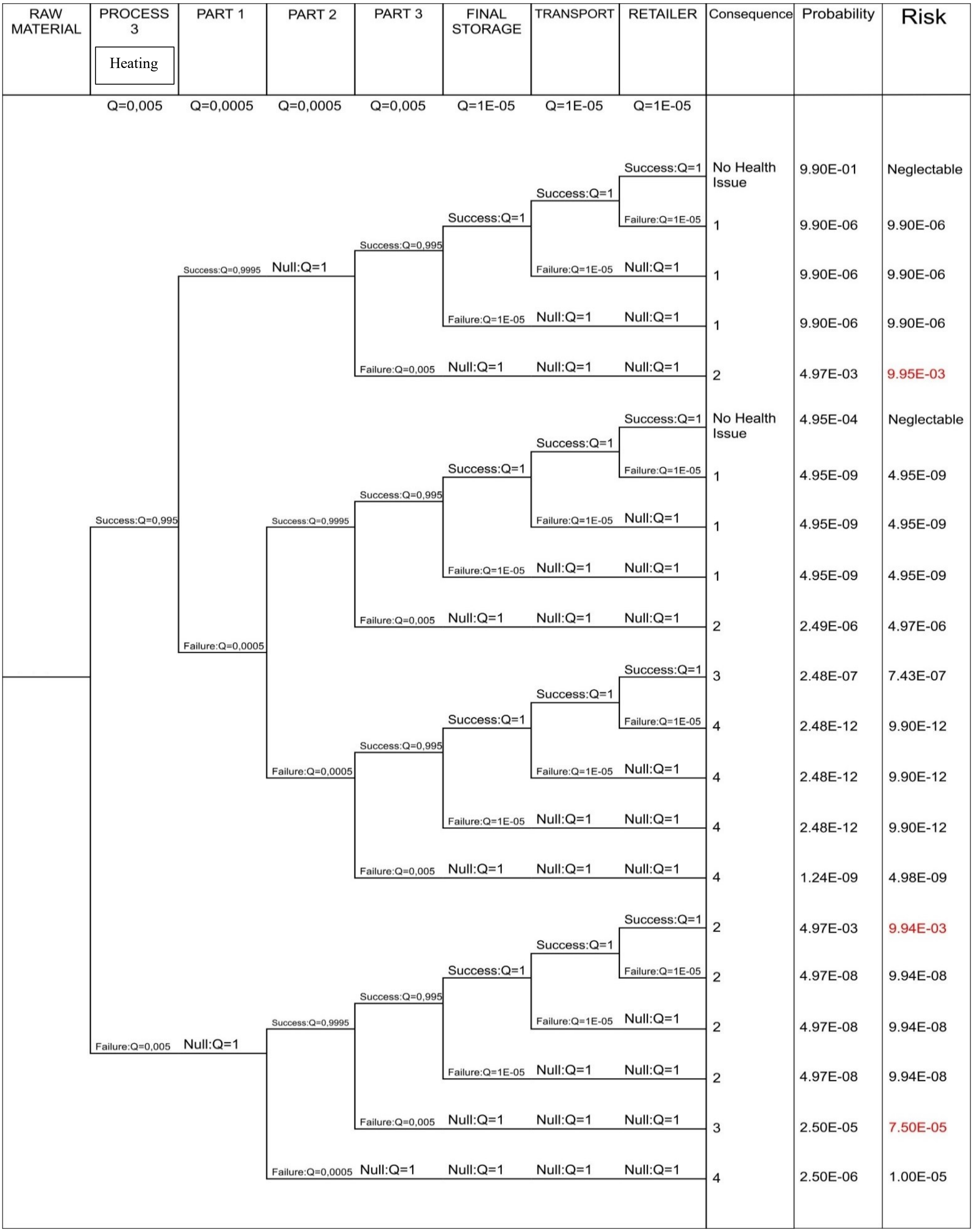

Figure 4:31: ETA of Ice-cream supply chain

Results of the ETA:

From the Event Tree Analysis (Figure 4:31) three pathways have been identified with high risk. The logic of assigning null for some events is the same as previous products (e.g. Milk, Yogurt) as they do not have major impact on the final consequences, neither increase nor decrease the severity levels. Furthermore, in each of these sequence there could be involvement of more than one supply chain stage (i.e. supplier, production, inventory, etc.). Thus, we need to measure the KPIs in each sequence in order to identify the critical point for intervention and reducing the risk.

1. Success in Process 3, Part 1, failure in Part 3, null in Pasteurization, Final storage, Transportation, Retailer. The total probability of 4,97E-03 and severity of 2, therefore the Risk (Probability*Consequence) of 9,95E-03.

Part 3 consists of Cooling, Adding Flavor and ingredient, and packaging with involvement of supplier and production. And as we can see in the KPIs measurement below the production has lower KPI index (280) comparing with supplier (350). Part 3 in Ice-cream process: supplier, production

Table 4:25: KPI measurement of Ice-cream process (involve: supplier, production)

KPI	KPI index	Weight	Results
S1	A	3	150
S2	A	3	150
S3	A	4	200
S4	E	3	-150
S5	C	4	0
Σ KPI Indicator			350
KPI	KPI index	Weight	Results
P1	D	3	-60
P2	C	1	0
P3	A	4	200
P4	A	4	200
P5	D	3	-60
Σ KPI Indicator			280

2. Failure in Process 3, null in Part 1, success in Pasteurization, Part 3, final storage,

transportation and retailer. The total probability of 4,97E-03 and severity of 2, therefore the Risk (Probability*Consequence) of 9,94E-03.

Process 3 or Heating process as mentioned in previous section includes homogenization and pasteurization process, with the KPI index in production (180).

Table 4:26: KPI measurement of Process 3: (production)

KPI	KPI index	Weight	Results
P1	A	4	200
P2	D	2	-40
P3	B	2	40
P4	B	2	40
P5	D	3	-60
Sum			180

3. Failure in Process 3, null in Part 1, success in Pasteurization, failure in Part 3, null in final storage, transportation and retailer. The total probability of 2,5E-05 and severity of 3, therefore the Risk (Probability*Consequence) of 7,5E-05.

Comparing KPIs of Process 3 and Part 3, we identify the lowest KPI index belongs to production in process 3 (180).

Final results:

Considering the ETA three sequences have risk limits above our threshold, and is due to failure in Part 3, or Process 3, or combination of both. These sections involve interference of Production, and Supplier. Therefore, we only measure the KPIs in these parts and based on KPIs data, the Process 3 has the lowest KPI safety index (180) following by production in Part 3 with KPI (280). Therefore, we can identify the most critical point in the Ice-cream production supply chain that is Pasteurization of raw milk and process of cooling and adding ingredients and flavors to the product and packaging the final product.
This result is also confirmed by the food outbreaks as well, because failure of the pasteurization or non-pasteurized ice-cream products is one of the main sources of safety outbreaks. Contamination of

the Ice-cream product after second pasteurization also could be at high risk and it could be associated with contamination with human contact during the process of adding flavors and packaging. This risk might not be reduced or eliminated in the following steps. Therefore, applying control points in these two stages and having more accurate quality checking beside food safety training for staff who are in direct contact with products are critical and recommended to reduce the probability of failure, and consequently reduction of the final risk of safety for consumers.

4.3 Conclusion for Case Study 1

As mentioned above the first case study in this research was in a dairy production company (company A), with four main products of milk, yogurt, cheese and ice-cream. There have been some specifications in case study 1 that need to be consider for testing and generalization of the research model as follow:

- Company A, is family-owned business, and categorized as an SME company with 10-12 employees.
- Its operation scale and market area is limited mainly in national level of north Italy.
- It covers the entire food supply chain from feed production, to the retailers. It includes all steps of supplier, production, inventory, transportation and retailer.
- The main potential food safety hazards in this company is biological hazards due to nature of the products (dairy products).

Considering the above specifications, the research model has been applied in all four products of company A. As it is described in section 3 phases 1 & 2 has been performed, taking advantage of multi-discipline approach by combination of ETA and KPIs. The food safety risk assessed along the supply chain for each product, and the results showed the critical safety point along the food supply chain and these results have been in alignment of food outbreaks statistics and history. The results of risk assessment act as an input for mitigating or reducing the risks in Risk Management step that is beyond the purpose of this research, and can be considered as a further study.

However, the final results presented to the company A, as well as some recommendation to reduce the risks. For example considering and adding critical points in HACCP, having accurate control point and quality checking, training the staff specifically those who are involve in critical points, applying IT (Information Technology) and central database in high risk points, specifically when human control failure can lead to food safety hazards.

5 Case Study 2: Iron Oxide Production for Food Additive

The second case study in this research is an international chemical processing manufacturing with more than 30 plants locations worldwide and over 4,500 employees. The case study location is in north Italy (for the purpose of confidentiality, we call it company B). There are diverse types of products in this company such as Inks, Personal care, Pharmaceuticals, Polymers, and Food ingredient synthetic iron oxide pigments.

Therefore, the product of this case study is synthetic iron oxide that is an ingredients designed to achieve opacity and color to enhance food and food-related products. With regards to the food safety, and other quality control certificates company B obtained certificates in ISO 9001, ISO 22000, and ISO 14000. The hazards chemical analysis performs internally by the company's biologist and externally through laboratory, in different time schedule depends on products types.

The interview performed with the quality control manager, process manager, and safety manager of the plant, with collaboration of risk assessor and supply chain specialist. In the first step the entire iron oxide operation has been viewed by the team, and has been mapped in details and complete process. The company B has not yet applied HACCP and risk assessment procedure, therefore, there was not much information about the Critical Control Point (CCP) and Control Point (CP). However, the operation is following GMP (Good Manufacturing Practice) and its standard procedure is applied in the process. The production process is mainly integrated with human factor contribution. In spite of that, human has a major role in controlling the system, in control room. Factors such as raw materials, PH and temperature, and pressure is constantly controlled and monitored by the specialists work in the control room to observe any abnormality in the entire production process.

The second step was to identify the probability and consequence of safety failure in each supply chain node, using the ETA. The ETA designed and performed with a team of food biologist, risk specialist, and chemist professors, plus quality manager in the company. The consequence of each failure in ETA have been identified using team experts opinions, and the probability has been recognized using food outbreak statistics, data from last events, check-lists and comparing to the current situation of the company B and expert opinion of interviewee in the company. In the third step the KPIs questionnaire have been answered by the interviewee, to identify the weakest point of each supply chain node in terms of food safety.

5.1 Background of the Iron Oxide production

By 18th century, Synthetic Red Iron Oxide pigments were initially manufactured in a laboratory setting and called as Mars Red. The properties of the pigments were similar to Natural Iron Oxide Pigments and the manufacturing of them started regularly from 19th century. (Cornell & Schwertmann, 2006)

As these pigments had properties such as durability, permanence etc., the developments of them were gradually proceeded, and for the first time, the yellow synthetic iron oxide called Mars Yellow were manufactured in the early 1920. Crucial developmental processes have been implemented during its production which still is proceeded as well. The producing of Brown Iron Oxide Pigments also has been developed by considering some modification in the production process of Mars Red and Mars Yellow. One of the main differences between Synthetic and Natural Iron Oxide pigments would be on their purity basis, as the Natural Iron Oxide Pigments include impurities which might decrease the working performance of the pigments.(Cornell & Schwertmann, 2006)

There are many applications for these pigments in the industries including wood and paper stains, linoleum, oilcloth, paints, mortar, plaster, bricks, rubber and also in color food, cosmetics and pharmaceutical products. It is worth mentioning that the synthetic Iron Oxide Pigments have a wider range of application in comparison with the Natural Iron Oxide Pigments and in some particular areas the application of Natural Iron Oxide Pigments cannot be replaced with the Synthetic Iron Oxide Pigments.

The finished natural or mined Iron Oxide Pigments (IOPs) were first manufactured by the United States sold approximately 87,800 metric tons (t) in 2000. This figure was 83,900 t for finished synthetic IOPs and totally the finished natural and synthetic IOPs were 172,000 t. The most consumption of these pigments was for construction (including for instance cement, mortar, and concrete), paints and coatings. (Hedin, 2003)

Any dye, pigment or other material that would be able to add color to a food, drug, or cosmetic or even human body is called by regulation as color additive. Color additives have crucial rule as one of the components of many products which can make them attractive, appealing, appetizing, and more informative. Color additives is applied as a type of code that let us to recognize products on sight, for instance candy flavors, medicine dosages, and left or right contact lenses. The assurance of safely and appropriately usage of the color additive is one of the duties of the U.S. Food and Drug Administration's (FDA, 2015).

Combined Compendium of Food Additive Specification publishes the iron oxides regulation, FAO JECFA Monographs 1(2010) (FAO/WHO, 2010). Firstly, low level of contamination by other metals as technical grades determines the food-quality iron oxides. This can be obtained by considering selection and control of the source of the iron or by monitoring the amount of chemical purification during the production process.

Considering Annex II to regulation (EC) No 1333/2008, the iron oxides and hydroxides would be authorized as food additives. In the EU in total fresh fruit and vegetables, maximum level of 6 mg/kg is allowed and considering quantum satis 48 food classification (Regulation (EC) No 1333/2008). (FAO/WHO, 2010; FOOD, 2007; Vin et al., 2013)

5.2 Production Process

Hematite is the source of natural iron oxides as a red iron oxide mineral; limonite, which change from yellow to brown, for example ochers, sienna, and umbers; and magnetite as a black iron oxide. Using basic chemical, synthetic iron oxide pigments are manufactured. Thermal decomposition of iron salts or iron compounds (calcining), precipitation of iron salts which are usually with oxidation, and reducing of organic compounds using iron are three main methods for the production of synthetic iron oxides (Cornell & Schwertmann, 2006).

Orange, red brown and yellow are the prevalent colors of the pigments. Iron salts or compounds should be decomposed, in order to manufacture synthetic iron oxide pigments. Synthetic pigments of iron oxide is produced by precipitating of iron salts and reduction of organic compounds by iron.

Red iron oxide ($Fe2O3$), yellow iron oxide ($FeO(OH)$), black iron oxide ($FeO \cdot Fe2O3$) and brown iron oxide which is a combination of the previous oxides are the food additive iron oxides and hydroxides (E172). Each type of iron oxide ($FeO \cdot Fe2O3$) would have various physical and chemical properties and can be applied as a combination or separately (brown iron oxide).

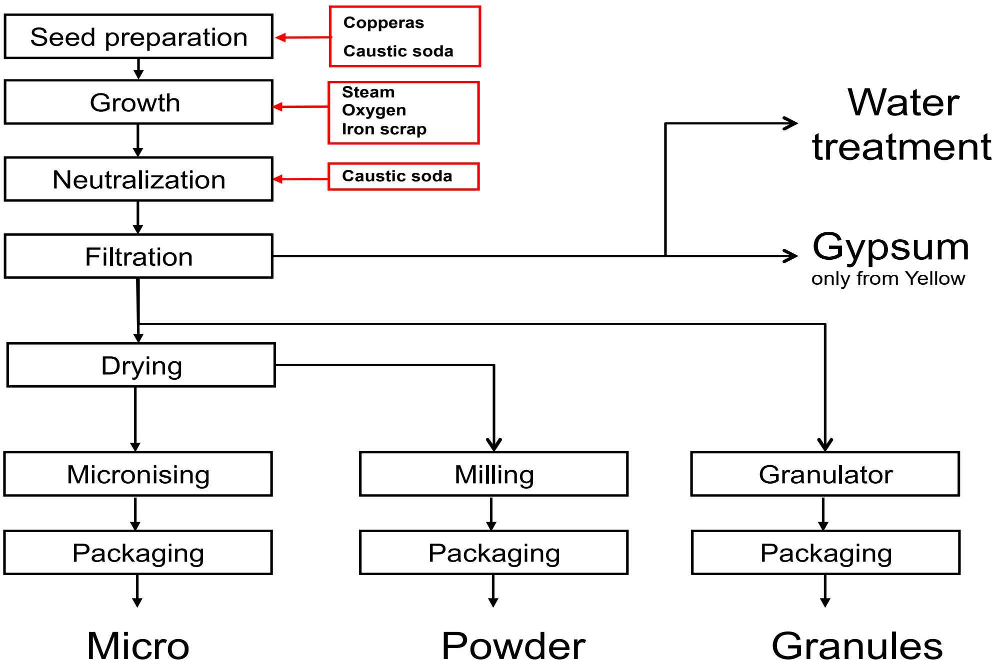

Figure 5:1: Production process of Iron Oxide

Synthetically from a ferrous salt, yellow iron oxide is manufactured, and by calcination of yellow iron oxide, red iron oxide is produced. Using chemical synthesis, the black iron oxide is reduced via a precipitation process that yellow iron oxide and red iron oxide would be the raw substances. Applying a blending process of yellow, red and black iron oxides, brown iron oxides would be manufactured. However, in this case study (company B) we only consider the production of Yellow iron oxide, and apply our risk assessment methodology to recognize the high risk safety node along the supply chain of this product.

The formulation of Yellow Iron Oxide process is as follow:

Equation 2: Seed Precipitation:

$$FeSO_4 + 2\,\mathrm{NaOH} \longrightarrow Fe(OH)_2 + Na_2SO_4$$
$$2\,\mathrm{Fe(OH)_2} + 1/2\,\mathrm{O_2} \longrightarrow 2\,\mathrm{FeO.OH\ (Yellow\ Seed)} + \mathrm{H_2}O$$
$$\longrightarrow \mathrm{Fe_2}O_3(\mathrm{Re}\,d\ \mathrm{Seed}) + 2\,\mathrm{H_2}O$$

Equation 3: Seed Growth:

$$2\,\mathrm{FeO \cdot OH} + 4\,\mathrm{Fe} + \mathrm{O_2} + 6H_2O \longrightarrow 6\,\mathrm{FeO \cdot OH} + 4\,\mathrm{H_2}$$
$$2\,\mathrm{Fe_2}O_3 + 8\mathrm{Fe} + 3\,\mathrm{O_2} + 6\mathrm{H_2}O \longrightarrow 6\,\mathrm{Fe_2}O_3 + 6H_2$$

The control points according to GMP of company B are mainly in the following stages:

- Raw material
- Temperature
- PH
- Redox Potential
- Iron Content

Company B manufactures precipitated iron oxide pigments by the Penniman-Zoph process.

Figure 5:2 describes the supply chain mapping of this product in company B.

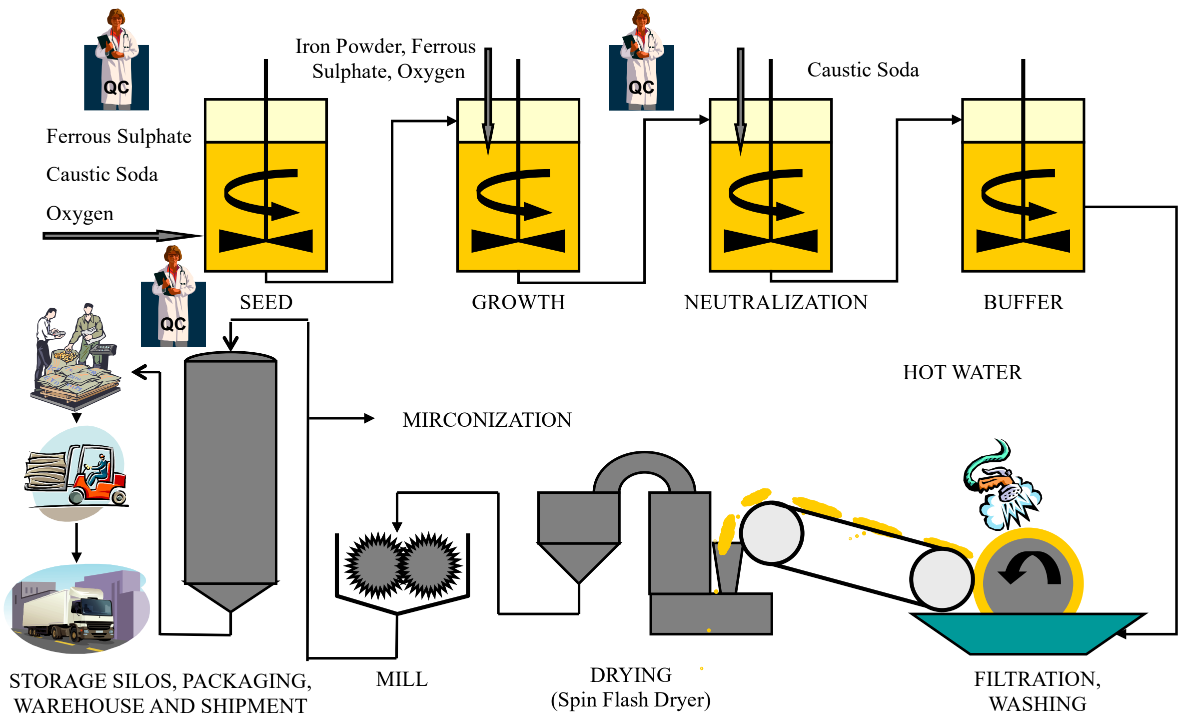

Figure 5:2: Supply chain of Iron Oxide production

Metallic iron reacts to yellow IO (oxygen from air, acids as catalysts); Critical raw materials include metallic iron and ferrous sulphate. For all critical starting materials, multiple supply chains exist from independent industrial sources in order to guarantee material availability.

A process for the production of iron oxide yellow pigments by the Penniman-Zoph process from the raw materials iron (II) sulphate (or $FeSO_4$), sodium hydroxide (NaOH) and metallic iron, is disclosed in which iron (II) is oxidized to iron (III) (or Fe_2O_3) by gassing with air in the presence of goethite

nuclei, the iron (III) sulfate is dissolved to form iron (II) and the goethite nuclei are built up to iron oxide yellow pigments. Red iron oxide is produced by calcination of yellow iron oxide.
Sodium hydroxide (NaOH), also known as caustic soda, is an Inorganic compound. It is a white solid and highly "Corrosive" metallic base which is available in number of different concentrations. It is a kind of corrosive acids and it can decompose proteins and lipids in living tissues via hydrolysis, and it could cause chemical burns upon un-protection contact during the production process.
Ferrous sulfate: or iron (II) sulphate is a salt with the formula $FeSO_4$. It is used medically to treat iron deficiency, and also for industrial applications. Swallowing of small amount is do not cause toxic effect. Swallowing a large amount leads to health problem like nausea, vomiting, diarrhea, and toxic action towards liver and kidneys follow.

5.3 Risk estimation

As Iron Oxide product is used as a small amount of raw material in other food products, it is not in direct contact with consumers. The hazard involved in this product is mainly Chemical hazards and in a lower extent Physical hazards (contamination of product with external physical objects during the process). As it is discussed in Table 2:6 chemical hazards in food could have reverse health impact on consumer in longer time period comparing to the biological and physical hazards. The hazards also depend on many other factors such as other processing before consumption, amount of consumption by end customer, age group of consumers, and many other factors.
However, a theoretical exposure scenario has been calculated by EFSA, considering that iron oxide would be only applied in food supplements, that causes in an intake up to 0.074 mg iron oxide/kg bw/day. It has been also mentioned by EFSA that the gamma irradiation of iron oxides (yellow, red, black and brown) has not been before evaluated neither by EFSA nor other Scientific Committees addressing foodstuffs, pharmaceutical products or cosmetics. (EFSA, 2015)
In this case study, the consequence of failure in each stage of supply chain has been identified considering the literature review on Iron Oxide and safety data sheet, and performed by the Risk Assessment team, involving quality control manager, and safety manager of the company, with collaboration of risk management, chemist, biologist, and supply chain specialist.
The probability of failure in each stage has been identified using the checklist of human error from Kirwan's generic guideline data (Table 5:1) because this production process is mainly performed by human either manually in raw materials combination, adding ferrous sulfate, and caustic soda; or

interaction of human and machine in packaging of final product or controlling the process (e.g. PH, Temperature).

Kirwan's generic guideline, provides information for probability of failure in tasks performed by human. It is typical judgment derived kinds of data that nevertheless provide acceptable guidelines for human reliability analysis as well. It is applicable in data from operational plants, ergonomics studies, and simulator studies.

According to the Table 5:1 the human error in the Iron oxide process is mainly in the group number 14 or Error in simple routine operation (HEP=1E -3). Simple routine operation, is a frequent task performed at the skill-based or rule-based level. There is no time pressure, however, the task may be embedded in a time pressure task scenario. Alternatively, if there is some urgency and stress involved in specific task, then it properly belongs to task 5 for which procedures are available.

Using the Table 5:1 for probability of failure estimation, and statistical data from literature and expert judgment for severity estimation, event tree diagram is drown and the risk of each pathway (or sequence) is analyzed in Figure 5:3.

Table 5:1: Generic guideline data for human error (Kirwan, 1994)

1	General rate for errors involving very high stress levels	0.3
2	Complicated non-routine task, with stress	0.3
3	Supervisor does not recognize the operators error	0.1
4	Non-routine operation, with other duties at the same time	0.1
5	Operator fails to act correctly in the first 30 minutes of a stressful situation	0.1
6	Errors in simple arithmetic with self-checking	0.03
7	General error rate for oral communication	0.03
8	Failure to return the manually operated test valve to the correct configuration after maintenance	0.01
9	Operator fails to act correctly after the first few hours in a high stress scenario	0.01
10	General error of omission	0.01
11	Error in a routine operation where care is required	0.01
12	Error of omission of an act embedded in a procedure	0.003
13	General error rate for an act performed incorrectly	0.003
14	Error in simple routine operation	0.001
15	Human-performance limit: single operator	0.0001
16	Human-performance limit: team of operators performing a well-designed task	0.00001

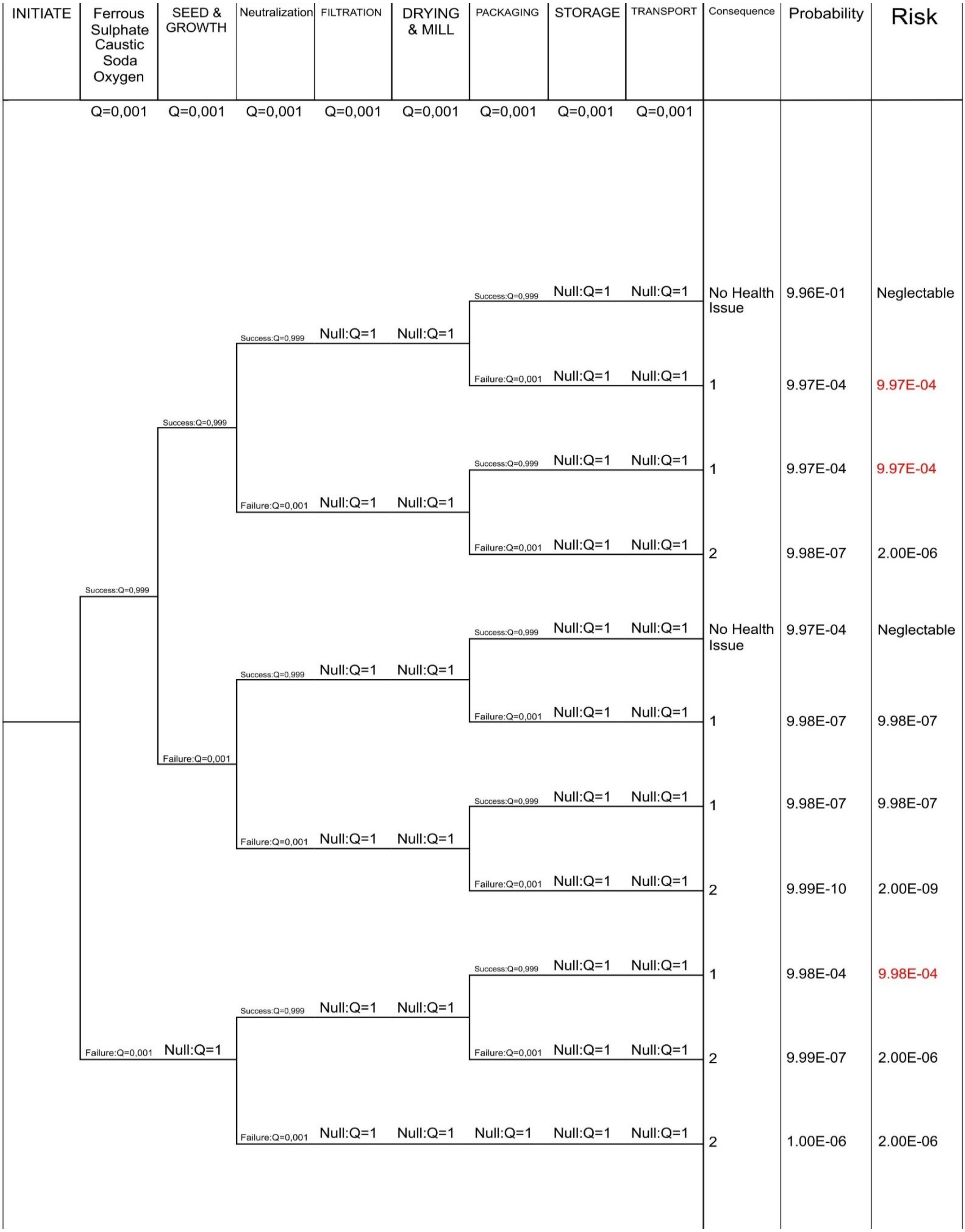

Figure 5:3: ETA of Iron Oxide

Results of the ETA

From the Event Tree Analysis (Figure 5:3) three pathways have been identified with high risk. In follow these three sequences are discussed and analyzed.

1. In pathway 1 we have success in Raw materials, Seed & Growth, Neutralization, Null in filtration and Drying as these steps might not have significant impact on the final consequence, failure in Packaging, null in Storage and Transportation. The total probability of 9,97E-04 and severity of 1, therefore the Risk (Probability*Consequence) of 9,97E-04.

Packaging involves interaction of suppliers (package product) and operation (Manually) and as we can see in the KPIs measurement below the supplier has lower KPI index (40) comparing with production (330).

Table 5:2: KPI measurement of packaging

KPI	KPI index	Weight	Results
S1	3	B	60
S2	4	C	0
S3	3	C	0
S4	1	D	-20
S5	3	C	0
Σ KPI Indicator			40
KPI	KPI index	Weight	Results
P1	4	C	0
P2	3	B	60
P3	3	B	60
P4	3	A	150
P5	3	B	60
Σ KPI Indicator			330

2. In pathway 2 we have success in Raw materials, Seed & Growth. And failure in Neutralization, Null in filtration and Drying as these steps might not have significant impact on the final consequence, success in Packaging, null in Storage and Transportation. The total

probability of 9,97E-04 and severity of 1, therefore the Risk (Probability*Consequence) of 9,97E-04.

Neutralization involves interaction of suppliers (Raw material Soda) and operation and as we can see in the KPIs measurement below the supplier has lower KPI index (40) comparing with production (330).

Table 5:3: KPI measurement in Neutralization process

KPI	KPI index	Weight	Results
S1	3	B	60
S2	4	C	0
S3	3	C	0
S4	1	D	-20
S5	3	C	0
Σ KPI Indicator			40
KPI	KPI index	Weight	Results
P1	4	C	0
P2	3	B	60
P3	3	B	60
P4	3	A	150
P5	3	B	60
Σ KPI Indicator			330

3. In pathway 3 we have failure in Raw materials, null in Seed & Growth, filtration and Drying. And success in Neutralization, Packaging. Seed & Growth assigned as Null because if there is safety failure in the raw materials, this step might not impact on the consequence to a large extent. The pathway has the total probability of 9,98E-04 and severity of 1, therefore the Risk (Probability*Consequence) of 9,98E-04.

Raw materials consists of ferrous sulphate, and Caustic soda and only supplier is involved in this step; therefore, there is no need for measurement of KPI in this pathway.

Final results:

As mentioned earlier based on ETA results, three sequences has risk limits above our threshold, and is due to failure in Packaging, Neutralization, and Raw materials. In all three sequences supplier have the lowest KPIs index and it shows in the Iron Dioxin supply chain, supplier is the weakest point in terms of food safety. These materials includes ferrous sulphate, and Caustic soda, as well as packaging products. This result is confirmed by the literature as well, because failure of raw materials in the food additives products is one of the main sources of chemical safety outbreaks. Therefore, it is suggested to have accurate quality control check for the raw materials from suppliers, and requirement for food safety certification or standards from suppliers.

5.4 Conclusion for Case Study 2

As mentioned above the second case study in this research was in a food additive production company (company B). There have been some specifications in case study 2 that need to be consider for testing and generalization of the research model as follow:

- Company B, is an international chemical processing manufacturing with over 4,500 employees.
- It has more than 30 plants locations worldwide and its market area is international and spread worldwide.
- Its operation includes production and inventory, other parts of supply chain are outsourced to other companies. Company B acts as a supplier of other food production companies, and does not have direct contact with end customers.
- The main potential food safety hazards in this company is chemical hazards due to nature of the products (Iron-Oxide).

Considering the above specifications, the research model has been applied in company B. As it is described in section 3, phases 1 & 2 has been performed, taking advantage of multi-discipline approach by combination of ETA and KPIs. The food safety risk assessed along the supply chain for Iron-oxide product, and the results showed the critical safety point along the food supply chain and these results have been in alignment of food outbreaks statistics and history.

The final results and some recommendation to reduce and mitigate the risks presented to the company B. For example quality control check for the raw materials from suppliers, and requirement for food safety standards from suppliers, due to high risk in raw material provided by suppliers. However, mitigating or reducing the risks covers by Risk Management step that is beyond the purpose of this research, and can be considered as a further study.

6 Final Conclusion

Research studies seeking to draw out the connection between food safety management systems and food outbreaks give an indication of defining characteristics of better performing firms, but they also reflect the methodological constraints relating to the measurement of integrated health and safety risk along the entire food supply chain. This problem has been addressed in this PhD thesis.

Food management systems are based on prevention by identifying where in the process the hazards are likely to occur and control them. It should be applicable throughout the food supply chain from raw material production through processing and distribution to final use by the consumer. Therefore, it requires an integrated approach, applicable among all the sections in the supply chain, while supporting decision makers by science based methods and accurate tools. Reviewing the three broad area of supply chain management, food safety management, and food safety risk assessment in chapter 2, made it clearer that “food supply chain risk assessment” has a multi-discipline domains that involve many activities and actors along the journey from farm to table. Therefore, the mere application of risk assessment tools in one or a few nodes of food supply chain will address only level problems without identifying and solving root cause in the food safety widen picture.

Thus, the first main result of this study is the development of a new methodology for food safety risk assessment that covers the entire supply chain, from raw material, production process, logistics, warehouse, and to the end consumers. This integrated approach was developed by intense review of previous methodologies in food safety and other high risk industries, as well as collaboration of multi discipline expertise, and food companies.

The developed model, benefit from combination of both collection survey in risk assessment method (i.e. ETA) and Performance Measurement tool (i.e. KPI). This integration enable decision makers to cover entire food supply chain and see the whole picture in terms of safety. In fact this new methodological approach has great importance for cooperation and interaction between different parties in the supply chain, as it is applicable in different sections and interface of agriculture, production, transport, storage and point of sales.

In the first phase of model, ETA provides quantitative risk assessment tool to identify the high risk sequence of event and evidence of the food safety risks in a reliable and transparent way. In the second phase, KPIs use semi-quantitative measurement, to recognize in which point of high risk sequence there is a need for intervention for risk reduction. Therefore, these two phases complete each other and establish an appropriate level of decision making tool.

Testing the model in two case studies to assess the reliability and applicability of the method in a practical environment. The method was tested in five different products, four products in SME and one product in large enterprise. The SME case study, operates in dairy production at farm level and family oriented business, while, large company case study operates in international level, production of food additives and chemical products. These companies, have been selected with very different scales and different types of products in order to test the accuracy and generalization of the model. The results of all analyses, was in alignment with previous literature and statistical data, and was approved by the specialists in research team and case companies as well.

In order to enable risk-based food safety management throughout the food chain, there have to be tools for every level. Although risk assessment tools mostly used by governmental bodies, this approach is also possible for food operators, both big and small. The developed model in this study, is beneficial for wide range of decision makers and companies that are involved in food production, without any limitation in size and operation of the company. It could be applicable in SMEs in farm level as well as large enterprise operating in food processing and manufacturing. Thereby this model contributes in the development of the food safety management systems by following points:

- With this semi-quantitative model a food safety manager can assess food safety risks that may occur in food production in order to help in choosing the Critical Control Points (CCPs) in HACCP or other food safety management standards; and therefore adjust hazard analysis towards a risk-based approach.
- The model assists in clarifying the magnitude of the food safety risks, in evaluating the functioning of the food safety. Thus, a company may prioritize its resources for food safety management, as well as allocate them effectively towards the processes and process steps with the greatest risk.
- It will facilitate the hazards monitoring, including rapid identification, visualisation and comparison, and position mapping in the food chain.
- It includes predictive models to identify ‘high-risk’ areas by analysis of the drivers of consequences, and their impact.
- It will ensure links and consistency with existing networks and standards of food industry to harmonised data collection, management and sharing and better management tools for authorities, and businesses.

- It could improve standardised processes at European and International level by using more harmonised and economical approach.

Therefore, this research collaborates in an interdisciplinary approach on a global scale by development of tools and methodologies for food risk assessment between authorities and firms. Improving the food safety will improve the public health, minimize market losses and facilitate international trade, thus increasing the competitiveness of the food and agricultural sector in national and international levels. Overall, the safety of the food chain will be reinforced and food security and sustainability will be enhanced.

7 References

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8 Appendix

8.1 Risk assessment tools (ISO 31000)

Type of risk assessment technique	Description	Relevance of influencing factors			Can provide Quantitative output
		Resources and capability	Nature and degree of uncertainty	Complexity	
LOOK-UP METHODS					
Check-lists	A simple form of risk identification. A technique which provides a listing of typical uncertainties which need to be considered. Users refer to a previously developed list, codes or standards	Low	Low	Low	No
Preliminary hazard analysis	A simple inductive method of analysis whose objective is to identify the hazards and hazardous situations and events that can cause harm for a given activity, facility or system	Low	High	Medium	No
SUPPORTING METHODS					
Structured Interview and brainstorming	A means of collecting a broad set of ideas and evaluation, ranking them by a team. Brainstorming may be stimulated by prompts or by one-on-one and one-on-many interview techniques	Low	Low	Low	No
Delphi technique	A means of combining expert opinions that may support the source and influence identification, probability and consequence estimation and risk evaluation. It is a collaborative technique for building consensus among experts. Involving independent analysis and voting by experts	Medium	Medium	Medium	No
SWIFT Structured "what-if")	A system for prompting a team to identify risks. Normally used within a facilitated workshop. Normally linked to a risk analysis and evaluation technique	Medium	Medium	Any	No
Human reliability analysis (HRA)	Human reliability assessment (HRA) deals with the impact of humans on system performance and can be used to evaluate human error influences on the system	Medium	Medium	Medium	Yes
SCENARIO ANALYSIS					
Root cause analysis (single loss analysis)	A single loss that has occurred is analysed in order to understand contributory causes and how the system or process can be improved to avoid such future losses. The analysis shall consider what controls were in place at the time the loss occurred and how controls might be improved	Medium	Low	Medium	No

Type of risk assessment technique	Description	Relevance of influencing factors			Can provide Quantitative output
		Resources and capability	Nature and degree of uncertainty	Complexity	
Scenario analysis	Possible future scenarios are identified through imagination or extrapolation from the present and different risks considered assuming each of these scenarios might occur. This can be done formally or informally qualitatively or quantitatively	Medium	High	Medium	No
Toxicological risk assessment	Hazards are identified and analysed and possible pathways by which a specified target might be exposed to the hazard are identified. Information on the level of exposure and the nature of harm caused by a given level of exposure are combined to give a measure of the probability that the specified harm will occur	High	High	Medium	Yes
Business impact analysis	Provides an analysis of how key disruption risks could affect an organization's operations and identifies and quantifies the capabilities that would be required to manage it	Medium	Medium	Medium	No
Fault tree analysis	A technique which starts with the undesired event (top event) and determines all the ways in which it could occur. These are displayed graphically in a logical tree diagram. Once the fault tree has been developed, consideration should be given to ways of reducing or eliminating potential causes / sources	High	High	Medium	Yes
Event tree analysis	Using inductive reasoning to translate probabilities of different initiating events into possible outcomes	Medium	Medium	Medium	Yes
Cause/ consequence analysis	A combination of fault and event tree analysis that allows inclusion of time delays. Both causes and consequences of an initiating event are considered	High	Medium	High	Yes
Cause-and-effect analysis	An effect can have a number of contributory factors which may be grouped into different categories. Contributory factors are identified often through brainstorming and displayed in a tree structure or fishbone diagram	Low	Low	Medium	No

Example type of risk assessment method and technique	Description	Relevance of influencing factors			Quantitative output possible?
CONTROLS ASSESSMENT					
LOPA (Layers of protection analysis	(May also be called barrier analysis). It allows controls and their effectiveness to be evaluated	Medium	Medium	Medium	Yes
Bow tie analysis	A simple diagrammatic way of describing and analysing the pathways of a risk from hazards to outcomes and reviewing controls. It can be considered to be a combination of the logic of a fault tree analysing the cause of an event (represented by the knot of a bow tie) and an event tree analysing the consequences	Medium	High	Medium	Yes
STATISTICAL METHODS					
Markov analysis	Markov analysis, sometimes called *State-space* analysis, is commonly used in the analysis of repairable complex systems that can exist in multiple states, including various degraded states	High	Low	High	Yes
Monte-Carlo analysis	Monte Carlo simulation is used to establish the aggregate variation in a system resulting from variations in the system, for a number of inputs, where each input has a defined distribution and the inputs are related to the output via defined relationships. The analysis can be used for a specific model where the interactions of the various inputs can be mathematically defined. The inputs can be based upon a variety of distribution types according to the nature of the uncertainty they are intended to represent. For risk assessment, triangular distributions or beta distributions are commonly used	High	Low	High	Yes
Bayesian analysis	A statistical procedure which utilizes prior distribution data to assess the probability of the result. Bayesian analysis depends upon the accuracy of the prior distribution to deduce an accurate result. Bayesian belief networks model cause-and-effect in a variety of domains by capturing probabilistic relationships of variable inputs to derive a result	High	Low	High	Yes

Example type of risk assessment method and technique	Description	Relevance of influencing factors			Quantitative output possible?
FUNCTION ANALYSIS					
FMEA and FMECA	FMEA (Failure Mode and Effect Analysis) is a technique which identifies failure modes and mechanisms, and their effects. There are several types of FMEA: Design (or product) FMEA which is used for components and products, System FMEA which is used for systems, Process FMEA which is used for manufacturing and assembly processes, Service FMEA and Software FMEA. FMEA may be followed by a criticality analysis which defines the significance of each failure mode, qualitatively, semi-qualitatively, or quantitatively (FMECA). The criticality analysis may be based on the probability that the failure mode will result in system failure, or the level of risk associated with the failure mode, or a risk priority number	Medium	Medium	Medium	Yes
Reliability-centred maintenance	A method to identify the policies that should be implemented to manage failures so as to efficiently and effectively achieve the required safety, availability and economy of operation for all types of equipment	Medium	Medium	Medium	Yes
Sneak analysis (Sneak circuit analysis)	A methodology for identifying design errors. A sneak condition is a latent hardware, software, or integrated condition that may cause an unwanted event to occur or may inhibit a desired event and is not caused by component failure. These conditions are characterized by their random nature and ability to escape detection during the most rigorous of standardized system tests. Sneak conditions can cause improper operation, loss of system availability, program delays, or even death or injury to personnel	Medium	Medium	Medium	No
HAZOP Hazard and operability studies	A general process of risk identification to define possible deviations from the expected or intended performance. It uses a guideword based system. The criticalities of the deviations are assessed	Medium	High	High	No
HACCP Hazard analysis and critical control points	A systematic, proactive, and preventive system for assuring product quality, reliability and safety of processes by measuring and monitoring specific characteristics which are required to be within defined limits	Medium	Medium	Medium	No

8.2 Questionnaire

Introduction:

Thank you for agreeing to be interviewed for this research.
The InnHF project is researching how human and organization factors and maintenance factors can be better integrated in to risk assessments. At this stage of the project we are aiming to understand how food companies trace their key performance indicators (KPI) and incorporate human and organizational factors.
The objective of today's interview is:

- ❖ To collect information about performance measurement in your food supply chain
- ❖ To collect information about the importance of different sections of the food supply chain

The interview will cover the following three areas:

- ❖ The background to the assessment
- ❖ The supply chain mapping
- ❖ The KPI in each node of the supply chain
- ❖ The importance of each KPI

PHASE I: SUPPLY CHAIN STRUCTURE

Please select which of the following supply chain steps are operated by your company.

☐ *Supplier* ☐ *Production* ☐ *Warehouse* ☐ *Transportation* ☐ Retailer

PHASE II: Key Performance Indicators

For each section of the supply chain we have defined a set of KPI, please complete the relevant table as follow:

- Please indicate the KPI which exist in the related section of the company (Or/ and) Based on the qualification measurement, based on your expert opinion.
- If you have a different KPI, how it is calculated and its value.

Supplier	KPI	Definition
S1	Product selection based on regulation or standards	This indicator measures the percentage of those products that are Listed on standards , or other approved product list, or standard treatment guidelines
S2	Percentage of Products that Undergo Quality Testing	This indicator measures the percentage of purchased individual products that undergo Quality testing
S3	Traceability	Information availability, use of barcodes, standardization of quality systems
S4	Order Compliance For each supplier	This indicator measures the percentage of orders that meet the set criteria (e.g., correct products received in the correct amounts)
S5	Human Factor	Competence of personnel in the food safety (HACCP, GMP, GAP)
Production	**Indicator**	**Definition**
P1	Percentage of Products that Undergo Quality Testing	This indicator measures the percentage of individual products/lots/shipments that undergo Quality testing
P2	Maintenance	Corrective maintenance to preventive maintenance ratio
P3	Traceability	Information availability, use of barcodes, standardization of quality systems
P4	Working conditions	Standard conditions that ensure a hygienic, safe working environment, with correct handling and good conditions

P5	Human Factor	Competence of personnel in the food safety (HACCP, GMP, GAP)
Inventory	**Indicator**	**Definition**
I1	Adequate Shelf Life	This measures the percentage of products received in a shipment with the pre-defined amount of shelf life
I2	Quality of products in the warehouse	The percentage of stock for a product that is in good quality and usable (not expiration or damage)
I3	Traceability	Information availability, use of barcodes, standardization of quality systems
I4	Storage conditions	Standard conditions required for storage of the products that are optimal for good quality
I5	Human Factor	Competence of personnel in the food safety (HACCP, GMP, GAP)
Transport	**Indicator**	**Definition**
T1	On-Time Arrivals To destination	This indicator measures the percentage of shipments arriving on time
T2	Percentage of Shipments Arriving in Good Condition	This indicator measures the percentage of shipments arriving in good condition without damage to the products
T3	Traceability	Information availability, use of barcodes, standardization of quality systems
T4	Storage and transport conditions	Standard conditions required for transportation and storage of the products that are optimal for good quality

T5	Human Factor	Competence of personnel in the food safety (HACCP, GMP, GAP)
Retailer	**Indicator**	**Definition**
R1	Customer satisfaction	Registered complaints from customers about product quality or safety
R2	Maintenance	Corrective maintenance to preventive maintenance ratio
R3	Traceability	Information availability, use of barcodes, standardization of quality systems
R4	Working conditions	Standard conditions required for storage and selling the products that are optimal for good quality
R5	Human Factor	Competence of personnel in the food safety (HACCP, GMP, GAP)

For each nodes of the supply chain the relevant KPIs need to be scales according to the following table:

Table 8:1: KPI measurement Index

KPI Scale	Definition	Quantitative Index
A	Very High	50
B	High	20
C	Medium	0
D	Low	-20
E	Neglectable	-50

And assigning weight (Table 3:7) for each KPI, in order to know which KPI has more importance regarding the level of food safety.

Table 8:2: Weight Index for each KPI

Weight Index	Scale
4	Critical
3	Important
2	Moderate
1	Low

PHASE III: Next step in the supply chain

- ❖ For the supply chain steps that are not covered by your company, could you give us relevant contact?
- ❖ Do you have any other information you would like to add?
- ❖ Are there any documents (internal standards, assessment templates, report templates) that you can give us to illustrate what we have been talking about today?

Information consent:

This interview is being conducted as part of a research project examining how performance indicators are incorporated in food safety with the aim of developing new methods and techniques to better address food safety issues.

Participation in the study is voluntary and there will be no consequences if you choose not to participate. You are free to withdraw at any time. All information obtained from the research will be anonymized during the analysis and it will not be used for any purposes other than this research.

The interview could be recorded in order to assist with data transcription and analysis. Only the research staff employed on the project will have access to the recording and transcript. The interview should last approximately two hours.

Further details on the project can be found at www.innhf.eu. Please ask the researcher if you have any further questions.

Consent

1. I confirm I have read and understood the above information and have had the opportunity to ask any further questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time.
3. I agree to take part in the study.

______________________	______________________	______________________
Name of Participant	Date	Signature
______________________	______________________	______________________
Name of Researcher	Date	Signature

Contact details

If you have any further queries or concerns after the interview, please contact:

Mohsen Shirani

InnHF Researcher

Politecnico di Torino - Corso Duca degli Abruzzi, 24 - 10129 Torino, ITALY

Tel: +39-3201722404

URL: http://www.innhf.eu/

<u>Demographics</u>

About you:

Please state your role/job title ____

How long have you been in this role? ________________________

How would you describe your knowledge of supply chain management?

☐ *Novice* ☐ *Competent* ☐ *Proficient* ☐ *Expert*

How would you describe your knowledge of KPI?

☐ *Novice* ☐ *Competent* ☐ *Proficient* ☐ *Expert*

Please indicate the industry in which you currently predominantly work and the number of years experience of Food Supply Chain Safety Management.

About your Company:

Approximately how many staff are employed by your company?

- Employees __________________
- Contractors (if any) __________________

8.3 Appendix 2: KPIs results from company A

Milking Process: supplier, production

KPI	KPI index	Weight	Results
S1	A	4	200
S2	B	3	60
S3	B	4	80
S4	B	3	60
S5	D	3	-60
Σ KPI Indicator			340
KPI	KPI index	Weight	Results
P1	B	4	80
P2	A	3	150
P3	B	2	40
P4	B	4	80
P5	D	3	-60
Σ KPI Indicator			290

Heating process: production

KPI	KPI index	Weight	Results
P1	A	4	200
P2	D	2	-40
P3	B	2	40
P4	B	2	40
P5	D	3	-60
Σ KPI Indicator			180

Milk process: supplier, production

KPI	KPI index	Weight	Results
S1	A	3	150
S2	A	3	150
S3	A	4	200
S4	E	3	-150
S5	C	2	0
Σ KPI Indicator			350
KPI	KPI index	Weight	Results
P1	D	3	-60
P2	C	1	0
P3	A	4	200
P4	A	4	200
P5	D	2	-40
Σ KPI Indicator			300

Yogurt process: supplier, production

KPI	KPI index	Weight	Results
S1	A	3	150

S2	A	3	150
S3	A	4	200
S4	E	3	-150
S5	C	3	0
Σ KPI Indicator			350
KPI	KPI index	Weight	Results
P1	B	3	60
P2	C	1	0
P3	A	4	200
P4	A	4	200
P5	D	3	-60
Σ KPI Indicator			400

Cheese process: supplier, production

KPI	KPI index	Weight	Results
S1	A	3	150
S2	A	3	150
S3	A	4	200
S4	E	3	-150
S5	C	4	0
Σ KPI Indicator			350
KPI	KPI index	Weight	Results
P1	D	3	-60
P2	C	1	0
P3	A	4	200
P4	A	4	200
P5	D	3	-60
Σ KPI Indicator			280

Ice-cream process: supplier, production

KPI	KPI index	Weight	Results
S1	A	3	150
S2	A	3	150
S3	A	4	200
S4	E	3	-150
S5	C	4	0
Σ KPI Indicator			350
KPI	KPI index	Weight	Results
P1	D	3	-60
P2	C	1	0
P3	A	4	200
P4	A	4	200
P5	D	3	-60
Σ KPI Indicator			280

8.4 Appendix 3: KPI results from company B

KPI	KPI index	Weight	Results
S1	3	B	60
S2	4	C	0
S3	3	C	0
S4	1	D	-20
S5	3	C	0
Σ KPI Indicator			40
KPI	KPI index	Weight	Results
P1	4	C	0
P2	3	B	60
P3	3	B	60
P4	3	A	150
P5	3	B	60
Σ KPI Indicator			330

KPI	KPI index	Weight	Results
I1	1	A	50
I2	4	B	80
I3	1	C	0
I4	3	B	60
I5	4	B	80
Σ KPI Indicator			270
KPI	KPI index	Weight	Results
T1	1	C	0
T2	3	C	0
T3	1	B	20
T4	3	C	0
T5	3	B	60
Σ KPI Indicator			80